CSR PLUG-IN FOR IUCLID 5.4 USER MANUAL

FEBRUARY 2013 - VERSION 4.1

PART II: SPECIFICATIONS OF THE CSR TEMPLATE

This part provides the Specifications of the CSR Template including the most relevant rules and conditions implemented in the CSR plug-in, unless described in the section "5.2. General rules".

CONVENTIONS

The following conventions are used:

- Placeholders for IUCLID 5 source fields are set between less than / greater than signs, i.e., <placeholder>. Example: <Reference substance name>.
- Annotations are set between brackets and formatted in italics. Examples:
  - *[IUCLID source: section 5.1.1 Phototransformation in air.*
    Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) disregarded study.]
  - *[IUCLID source: Endpoint summary 5.1.1 Phototransformation in air.]*
  - *[If field "Type of method" = "in vitro".]*
- Rules described in Part I of this User's Guide, section "5 Format and general rules underlying the CSR generation" are normally not repeated. Please refer to that section.

CHEMICAL SAFETY REPORT

Substance Name: <Reference substance name>

Substance Name: <Chemical name> *[If no <Reference substance name> available.]*

EC Number: <Chemical name>

CAS Number: <CAS number (EC inventory)>

CAS Number: <CAS number (CAS information)> *[Only if no CAS number (EC inventory) available.]*

Registrant's Identity: <Legal entity name>

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Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

[IUCLID source: section 1.1 Identification, unless otherwise stated]

[Depending on the values of IUCLID fields "Composition" and "Origin" one of the following statements is automatically inserted.]

The substance <Reference substance name/Chemical name> is an element having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details). *[If field "Origin" = "element"]*

The substance <Reference substance name/Chemical name> is a <Composition> (<Origin>) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details). *[If field "Composition" <> "other:" or <> empty and field "Origin" <> "element".]*

Type of substance <Reference substance name/Chemical name>: <Composition> (composition)[; <Origin> (origin)]. The characteristics and physical–chemical properties are described below (see the IUCLID dataset for further details). *[If field "Composition" = "other:" or empty and field "Origin" <> "element".]*

The following public name is used: <Public name> *[New field in IUCLID 5.2]*

Table 1. Substance identity

EC number:	<EC number>
EC name:	<EC name>
CAS number (EC inventory):	<CAS number (EC inventory)>
CAS number:	<CAS number> *[If different from <CAS number (EC inventory)>]*
CAS name:	<CAS name>
IUPAC name:	<IUPAC name>
Description:	<Description> *[Only if none of the standard identifiers are available]*
Synonyms:	<Synonyms>*[Only if none of the standard identifiers are available]*
Annex I index number:	<Index number> *[Source: 2.2 DSD - DPD: General information]*
Molecular formula:	<Molecular formula>
Molecular weight range:	<RANGE: Molecular weight range>

Structural formula:

[Any image included in the field "Structural formula" is captured and transferred into the CSR template.]

Remarks:

<Remarks>

1.2. Composition of the substance

[IUCLID source: section 1.2 Composition]

Name: <Name>

Description: <Brief description>

Degree of purity: <Degree of purity>

Table 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
<Reference substance> EC no.: <EC number>	<Typical concentration, qualifier> <Typical concentration, value> <Typical concentration, unit>	<Concentration range>	<Remarks>

Table 3. Impurities

Impurity	Typical concentration	Concentration range	Remarks
<Reference substance> EC no.: <EC number>	<Typical concentration, qualifier> <Typical concentration, value> <Typical concentration, unit>	<Concentration range>	**Impurity is relevant for C&L of the substance** *[Insert if this checkbox is selected.]* <Remarks>

Table 4. Additives

Additive	Function	Typical concentration	Concentration range	Remarks
<Reference substance> EC no.: <EC number>	<Function>	<Typical concentration, qualifier> <Typical concentration, value> <Typical concentration, unit>	<Concentration range>	**Additive is relevant for C&L of the substance** *[Insert if this checkbox is selected.]* <Remarks>

1.3. Physicochemical properties

[IUCLID source: endpoint summary records of sections 4.1 Appearance/physical state/colour / 4.2 Melting point/freezing point / 4.3 Boiling point / 4.4 Density / 4.5 Particle size distribution (Granulometry) / 4.6 Vapour pressure / 4.7 Partition coefficient / 4.8 Water solubility / 4.9 Solubility in organic solvents / fat solubility / 4.10 Surface tension / 4.11 Flash point / 4.12 Auto flammability / 4.13 Flammability / 4.14 Explosiveness / 4.15 Oxidising properties / 4.16 Oxidation reduction potential / 4.17 Stability in organic solvents ... / 4.18 Storage stability and reactivity ... / 4.19 Stability: thermal, sunlight, metals / 4.21 Dissociation constant / 4.22 Viscosity]

No relevant information available *[Rule: Print if none of the following kind of information is available: (i) endpoint summary information; (ii) value from field "Physical state" of any endpoint study record of IUCLID section 4.1; (iii) entry in field "Data waiving"; (iv) "experimental study planned" in field "Study result type".]*

Table 5. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	<Short description of key information> *[Alternative source: endpoint study record(s), if no endpoint summary value is available for "Physical state ":* *<Physical state at 20ºC and 1013 hPa>* *<Form> / Colour: <Colour> / <Odour>* *(source: endpoint study record(s)]*	**Value used for CSA:** <Physical state at 20°C and 1013 hPa> at 20°C and 101.3 kPa <Discussion>
Melting / freezing point	<Short description of key information>	**Value used for CSA:** <Melting / freezing point> <Unit> at 101.3 kPa <Discussion>
Boiling point	<Short description of key information>	**Value used for CSA:** <Boiling point> <Unit> at 101.3 kPa <Discussion>
Relative density	<Short description of key information>	**Value used for CSA:** <Relative density> at 20°C <Discussion>
Granulometry	<Short description of key information>	<Discussion>
Vapour pressure	<Short description of key information>	**Value used for CSA:** <Vapour pressure> <Unit> at <Temp.> <Unit> <Discussion>
Partition coefficient n-octanol/water (log value)	<Short description of key information>	**Value used for CSA:** Log Kow (Log Pow): <Log Kow (Log Pow)> at <Temp.> <Unit> <Discussion>
Water solubility	<Short description of key information>	**Value used for CSA:** <Water solubility> <Unit> at <Temp.> <Unit> <Discussion>
Solubility in organic solvents / fat solubility	<Short description of key information>	**Value used for CSA:** Solubility in mg/100 g standard fat at 20°C: <Solubility in mg/100 g standard fat at 20°C> Solubility in organic solvents at 20°C: <Solubility in organic solvents at 20°C> <Discussion>
Surface tension	<Short description of key information>	**Value used for CSA:** <Surface tension> mN/m at 20°C and <Conc.> mg/L <Discussion>
Flash point	<Short description of key information>	**Value used for CSA:** <Flash point> <Unit> at 1013 hPa <Discussion>
Autoflammability / self-ignition temperature	<Short description of key information>	**Value used for CSA:** <Autoflammability / Self-ignition temperature> <Unit> at 1013 hPa <Discussion>
Flammability	<Short description of key information>	**Value used for CSA:** <Flammability> <Discussion>

Explosive properties	<Short description of key information>	**Value used for CSA:** <Explosiveness> <Discussion>
Oxidising properties	<Short description of key information>	**Value used for CSA:** Oxidising: <Oxidising> <Discussion>
Oxidation reduction potential	<Short description of key information>	**Value used for CSA:** Oxidation reduction potential in mV at 20°C: <Oxidation reduction potential in mV at 20°C> <Discussion>
Stability in organic solvents and identity of relevant degradation products	<Short description of key information>	<Discussion>
Storage stability and reactivity towards container material	<Short description of key information>	<Discussion>
Stability: thermal, sunlight, metals	<Short description of key information>	<Discussion>
Dissociation constant	<Short description of key information>	**Value used for CSA:** pKa at 20°C: <pKa at 20°C> <Discussion>
Viscosity	<Short description of key information>	**Value used for CSA:** Viscosity at 20°C: <Viscosity at 20°C> <Unit> <Discussion>

Data waiving

[IUCLID source: endpoint study records of sections 4.2 Melting point/freezing point / 4.3 Boiling point / 4.4 Density / 4.5 Particle size distribution (Granulometry) / 4.6 Vapour pressure / 4.7 Partition coefficient / 4.8 Water solubility / 4.9 Solubility in organic solvents / fat solubility / 4.10 Surface tension / 4.11 Flash point / 4.12 Auto flammability / 4.13 Flammability / 4.14 Explosiveness / 4.15 Oxidising properties / 4.16 Oxidation reduction potential / 4.17 Stability in organic solvents ... / 4.18 Storage stability and reactivity ... / 4.19 Stability: thermal, sunlight, metals / 4.21 Dissociation constant / 4.22 Viscosity]

Information requirement: Melting / freezing point

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Boiling point

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Relative density

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Granulometry

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Vapour pressure

Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Partition coefficient n-octanol/water (log value)
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Water solubility
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Solubility in organic solvents / fat solubility
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Surface tension
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Flash point
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Self-ignition temperature
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Flammability
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Explosive properties
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Oxidising properties
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Oxidation reduction potential
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Stability in organic solvents and identity of relevant degradation products
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Reactivity towards container material
Reason: <Data waiving>
Justification: <Justification for data waiving>

Information requirement: Thermal stability

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Dissociation constant

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Viscosity

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

[IUCLID source: as for Data waiving; see above]

Information requirement: Melting / freezing point

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Boiling point

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Relative density

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Granulometry

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Vapour pressure

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Partition coefficient n-octanol/water (log value)

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Water solubility

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Solubility in organic solvents / fat solubility

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Surface tension

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Flash point

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Self-ignition temperature

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Flammability

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Explosive properties

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Oxidising properties

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Oxidation reduction potential

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Stability in organic solvents and identity of relevant degradation products

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Reactivity towards container material

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Thermal stability

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Dissociation constant

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Information requirement: Viscosity

Proposed test guideline: <Guideline>

Planned type of method: <Type of method>

Principles of method if other than guideline:

<Principles of method if other than guideline>

<Any other information on materials and methods incl. tables>

Planned study period: <Study period>

Discussion of physicochemical properties

<Discussion> *[IUCLID source: Endpoint summary: 4. Physical and chemical properties]*

2. MANUFACTURE AND USES

No information available on quantities *[Rule: Print if none of the specified fields is populated.]*

Table 6. Quantities (in tonnes/year)
[IUCLID source: section 3.2 Estimated quantities]

Year	Total tonnage	Uses exempted from CSR	Used for article
<Year>	Manufactured: <Manufactured> Imported: <Imported> Directly exported: <Directly exported>	Uses as intermediate under strictly controlled conditions (on-site): <Tonnage used as intermediate under strictly controlled conditions (on-site)> Used as intermediate under strictly controlled conditions (transported): <Tonnage used as intermediate under strictly controlled conditions (transported)> Used for research purposes: <Tonnage used for research purposes>	Imported in articles: <Tonnage imported in articles> Tonnage in produced articles: <Tonnage in produced articles>

<Remarks>

2.1. Manufacture

No information available on manufacture *[Rule: Print if none of the specified fields is populated.]*

Table 7. Manufacture
[IUCLID source: section 3.5 Life Cycle description. Rule: Create a row for each item of the repeatable block "Manufacture"]

Identifiers	Use descriptors	Other information
Confidential:*[Rule: Print if Confidentiality flag = CBI]* M-<Manufacture number>: <Manufacture name> *[e.g. Confidential: M-1: Manufacture of the substance]*	• **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC):** <Process Category> *[Rule: Print multiple PROCs separated by semicolon, e.g. PROC 1; PROC 8a]*	Tonnage of substance for that use: <Tonnage of substance > tonnes Number of sites: <Number of sites range> Remarks: <Remarks>

No information available on manufacturing process related to the specified manufacture(s) *[Rule: Print if none of the specified fields is populated.]*

Table 8. Manufacturing process related to the specified manufacture(s)
[IUCLID source: section 3.1 Technological process; Rule: Print if at least one source field "Methods of manufacture of substance" is populated]

Related manufacture(s)	**Description of manufacturing process**
<Related manufacture>	<Methods of manufacture of substance>

[Rule 1: Print table if at least one source field "Methods of manufacture of substance" is populated.
Rule 2: Print separate rows for each "Methods of manufacture of substance".
Rule 3: Print all "Related manufacture" values, concatenated with the use type (i.e. "M") and manufacture number."
Example:]

Related manufacture(s)	***Description of manufacturing process***
M-1: Production of … *M-2: Production of …*	*Freetext .....*
M-: Production of …	*Freetext .....*

No information available on production of articles covered by the specified use(s) *[Rule: Print if none of the specified fields is populated.]*

Table 9. Method of production of articles covered by the specified use(s)
[IUCLID source: section 3.1 Technological process; Rule: Print if at least one source field "Methods of article production" is populated]

Related use(s)	**Description of article production process**
<Related use>	<Methods of article production>

[Rules: as above for "Manufacturing process"]

[Please note: If the link of any related manufacture or use was deleted in the IUCLID source dataset, nothing can be output in either of the tables above. This can happen either by intentionally removing the link in IUCLID section 3.1 or by pasting IUCLID section 3.1 from the IUCLID clipboard.
Tip: If section 3.5 containing the referenced uses are pasted first, followed by section 3.1, the links are kept.]

2.2. Identified uses

[IUCLID source: section 3.5 Life Cycle description, if not otherwise stated]

Justification why no identified uses are reported: <Justification why no identified uses are reported>

No information available *[Rule: Print if none of the specified fields is populated in this section.]*

Table 10. Formulation
[IUCLID source: section 3.5 Life Cycle description. Rule: Create a row for each item of the repeatable block "Formulation"]

Identifiers	**Use descriptors** *[Rule: Print multiple items in separate lines]*	**Other information**
Confidential:*[Rule: Print if Confidentiality flag = CBI]* F-<Identified use number>: <Identified use name> *[e.g. F-2: Formulation of liquid mixtures]*	• **Environmental Release Category (ERC)**: <ERC> • **Process Category (PROC):** <Process Category> • **Product Category formulated:** <Product Category formulated> • **Technical function of the substance during formulation:** <Technical function of the substance during formulation>	Tonnage of substance for that use: <Tonnage of substance > tonnes Number of sites: <Number of sites range> Substance supplied to that use: <Substance supplied to that use in form of> *[Rule: Print multiple items in separate lines]* Remarks: <Remarks>

Table 11. Uses at industrial sites
[IUCLID source: section 3.5 Life Cycle description. Rule: Create a row for each item of the repeatable block "Uses at industrial sites"]

Identifiers	**Use descriptors** *[Rule: Print multiple items in separate lines]*	**Other information**
Confidential:*[Rule: Print if Confidentiality flag = CBI]* IW-<Identified use number>: <Identified use name>	• **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC):** <Process Category> • **Product Category used:** <Product Category used> • **Sector of end use:** <Sector of end use> • **Technical function of the substance:** <Technical function of the substance>	Tonnage of substance for that use: <Tonnage of substance > tonnes Number of sites: <Number of sites range> Substance supplied to that use: <Substance supplied to that use in form of> *[Rule: Print multiple items in separate lines]* Subsequent service life relevant for that use: <Subsequent service life relevant for that use?> Link to the subsequent service life: <Link to the subsequent service life> *[Rule: Print multiple items in separate lines]* Remarks: <Remarks>

Table 12. Uses by professional workers
[IUCLID source: section 3.5 Life Cycle description. Rule: Create a row for each item of the repeatable block "Uses by professional workers"]

Identifiers	**Use descriptors** *[Rule: Print multiple items in separate lines]*	**Other information**
Confidential:*[Rule: Print if Confidentiality flag = CBI]* PW-<Identified use number>: <Identified use name>	• **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC):** <Process Category> • **Product Category used:** <Product Category used> • **Sector of end use:** <Sector of end use> • **Technical function of the substance:** <Technical function of the substance>	Tonnage of substance for that use: <Tonnage of substance > tonnes Substance supplied to that use: <Substance supplied to that use in form of> *[Rule: Print multiple items in separate lines]* Subsequent service life relevant for that use: <Subsequent service life relevant for that use?> Link to the subsequent service life: <Link to the subsequent service life> *[Rule: Print multiple items in separate lines]* Remarks: <Remarks>

Table 13. Consumer uses
[IUCLID source: section 3.5 Life Cycle description. Rule: Create a row for each item of the repeatable block "Consumer uses"]

Identifiers	**Use descriptors** *[Rule: Print multiple items in separate lines]*	**Other information**
Confidential:*[Rule: Print if Confidentiality flag = CBI]* C-<Identified use number>: <Identified use name>	• **Environmental Release Category (ERC):** <ERC> • **Product Category used:** <Product Category used> • **Technical function of the substance:** <Technical function of the substance>	Tonnage of substance for that use: <Tonnage of substance > tonnes Substance supplied to that use: <Substance supplied to that use in form of> *[Rule: Print multiple items in separate lines]* Subsequent service life relevant for that use: <Subsequent service life relevant for that use?> Link to the subsequent service life: <Link to the subsequent service life> *[Rule: Print multiple items in separate lines]* Remarks: <Remarks>

Table 14. Article service life
[IUCLID source: section 3.5 Life Cycle description. Rule: Create a row for each item of the repeatable block "Article service life"]

Identifiers	**Use descriptors** *[Rule: Print multiple items in separate lines]*	**Other information**
Confidential:*[Rule: Print if Confidentiality flag = CBI]* SL-<Service life number>: <Service life name>	• **Article category related to subsequent service life (AC):** <Article category related to subsequent service life> • **Exposure related description of article:** <Exposure related description of article> • **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC) for articles used by workers:** <Process Category for articles used by workers> • **Technical function of the substance:** <Technical function of the substance>	Article used by: <Article used by>*[Rule: Print multiple items in separate lines]* Tonnage of substance for that use: <Tonnage of substance > tonnes Typical concentration of the substance in article: <Typical concentration of the substance in article (%)> % Remarks: <Remarks>

2.3. Uses advised against

[IUCLID source: section 3.6 Uses advised against]

No information available *[Rule: Print if none of the specified fields is populated in this section.]*

Table 15. Formulation
[Rules as stated for the corresponding table in the previous section]

Identifiers	**Use descriptors**	**Other information**
Confidential:*[Rule: Print if Confidentiality flag = CBI]* F-<Identified use number>: <Identified use name> *[e.g. F-2: Formulation of liquid mixtures]*	• **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC):** <Process Category> • **Product Category formulated:** <Product Category formulated> • **Technical function of the substance during formulation:** <Technical function of the substance during formulation>	Remarks: <Remarks>

Table 16. Uses at industrial sites
[Rules as stated for the corresponding table in the previous section]

Identifiers	Use descriptors	Other information
Confidential:*[Rule: Print if Confidentiality flag = CBI]* IW-<Identified use number>: <Identified use name>	• **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC):** <Process Category> • **Product Category used:** <Product Category used> • **Sector of end use:** <Sector of end use> • **Technical function of the substance:** <Technical function of the substance>	Remarks: <Remarks>

Table 17. Uses by professional workers
[Rules as stated for the corresponding table in the previous section]

Identifiers	Use descriptors	Other information
Confidential:*[Rule: Print if Confidentiality flag = CBI]* PW-<Identified use number>: <Identified use name>	• **Environmental Release Category (ERC):** <ERC> • **Process Category (PROC):** <Process Category> • **Product Category used:** <Product Category used> • **Sector of end use:** <Sector of end use> • **Technical function of the substance:** <Technical function of the substance>	Remarks: <Remarks>

Table 18. Consumer uses
[Rules as stated for the corresponding table in the previous section]

Identifiers	Use descriptors	Other information
Confidential:*[Rule: Print if Confidentiality flag = CBI]* C-<Identified use number>: <Identified use name>	• **Environmental Release Category (ERC):** <ERC> • **Product Category used:** <Product Category used> • **Technical function of the substance:** <Technical function of the substance>	Remarks: <Remarks>

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

[IUCLID source: section 2.1 GHS]

No relevant information available *[Rule: Print if none of the fields specified below is populated and the checkbox "not classified" is not ticked. Note: This default text is not printed if any field "Reason for no classification" is populated with the IUCLID default phrase "data lacking".]*

Substance: <Name> *[Alternatively: Substance: <Reference substance name>, if <Name> is blank.]*

Implementation: <Implementation>

State/form of the substance: <State/form of the substance>

Remarks: <Remarks>

Classification

The substance is not classified *[Rule: Print if the checkbox "not classified" is selected.]*

The substance is classified as follows: *[Rule: Print if either of the "Classification" fields is populated. Rule 2: This also triggers the output of the following table(s). Rule 3: Print each item (row) if any of the fields ("Hazard category", "Hazard statement", "Reason for no classification") is populated.]*

Table 19. Classification and labelling according to CLP / GHS for physicochemical properties

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:	<category>	<hazardStatement>	<reasonForNoClassification>	6.1
Flammable gases:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2
Flammable aerosols:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2
Oxidising gases:	<category>	<hazardStatement>	<reasonForNoClassification>	6.3
Gases under pressure:	<category>	<hazardStatement>	<reasonForNoClassification>	
Flammable liquids:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2
Flammable solids:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2
Self-reactive substances and mixtures:	<category>	<hazardStatement>	<reasonForNoClassification>	
Pyrophoric liquids:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2
Pyrophoric solids:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2

Self-heating substances and mixtures:	<category>	<hazardStatement>	<reasonForNoClassification>	
Substances and mixtures which in contact with water emit flammable gases:	<category>	<hazardStatement>	<reasonForNoClassification>	6.2
Oxidising liquids:	<category>	<hazardStatement>	<reasonForNoClassification>	6.3
Oxidising solids:	<category>	<hazardStatement>	<reasonForNoClassification>	6.3
Organic peroxides:	<category>	<hazardStatement>	<reasonForNoClassification>	
Corrosive to metals:	<category>	<hazardStatement>	<reasonForNoClassification>	

*) Justification for (non) classification can be found in the CSR section indicated

Table 20. Classification and labelling according to CLP / GHS for health hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:	<category>	<hazardStatement>	<reasonForNoClassification>	5.2.3
Acute toxicity - dermal:	<category>	<hazardStatement>	<reasonForNoClassification>	5.2.3
Acute toxicity - inhalation:	<category>	<hazardStatement>	<reasonForNoClassification>	5.2.3
Skin corrosion / irritation:	<category>	<hazardStatement>	<reasonForNoClassification>	5.3.4 and 5.4.3
Serious damage / eye irritation:	<category>	<hazardStatement>	<reasonForNoClassification>	5.3.4
Respiration sensitization:	<category>	<hazardStatement>	<reasonForNoClassification>	5.5.3
Skin sensitation:	<category>	<hazardStatement>	<reasonForNoClassification>	5.5.3
Aspiration hazard:	<category>	<hazardStatement>	<reasonForNoClassification>	5.2.3
Reproductive Toxicity:	<category> Specific effect: <Specific effect> Route of exposure: <Route of exposure>	<hazardStatement>	<reasonForNoClassification>	5.9.3
Reproductive Toxicity: Effects	<category>	<hazardStatement>	<reasonForNoClassification>	5.9.3

on or via lactation:				
Germ cell mutagenicity:	<category> Route of exposure: <Route of exposure>	<hazardStatement>	<reasonForNoClassification>	5.7.3
Carcinogenicity:	<category> Route of exposure: <Route of exposure>	<hazardStatement>	<reasonForNoClassification>	5.8.3
Specific target organ toxicity - single:	<category> Affected organs: <Affected organs> Route of exposure: <Route of exposure>	<hazardStatement>	<reasonForNoClassification>	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:	<category> Affected organs: <Affected organs> Route of exposure: <Route of exposure>	<hazardStatement>	<reasonForNoClassification>	5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

Specific concentration limits:

Concentration (%)	**Classification**
<Concentration range>	<Hazard categories>

Table 21. Classification and labelling according to CLP / GHS for the environment

Endpoint	**Hazard category**	**Hazard statement**	**Reason for no classification**	**CSR section*)**
Hazards to the aquatic environment (acute/short-term):	<category>	<hazardStatement>	<reasonForNoClassification>	7.6
Hazards to the aquatic environment (long-term):	<category>	<hazardStatement>	<reasonForNoClassification>	7.6
M-Factor acute: <mfactor acute>				
M-Factor chronic: <mfactor chronic>				
Hazardous to the ozone layer:	<category>	<hazardStatement>	<reasonForNoClassification>	7.6

*) Justification for (non) classification can be found in the CSR section indicated

Table 22. Classification and labelling according to CLP / GHS for additional hazard classes

Additional hazard classes:	<Additional hazard classes>

Additional hazard statements:	<Additional hazard statements>

Labelling

Signal word: <Signal word>

Hazard pictogram:

<Hazard pictogram>

Hazard statements:

<Hazard statement> (<Additional text>)

Precautionary statements:

<Precautionary statement> (<Additional text>)

Additional labelling requirements (CLP supplemental hazard statement):

<CLP supplemental hazard statement> (Additional text: <Additional text>)

<Additional labelling>

Notes:

<Notes>

3.2. Classification and labelling according to DSD / DPD

3.2.1 Classification and labelling in Annex I of Directive 67/548/EEC

[IUCLID source: section 2.2 DSD - DPD; condition: if field "Status" = "67/548/EEC annex 1".]

No relevant information available *[Rule: Print if none of the fields specified below is populated and the checkbox "not classified" is not ticked. Note: This default text is not printed if any field "Reason for no classification" is populated with the IUCLID default phrase "data lacking".]*

Chemical name: <Name> *[Alternatively: Substance: <Reference substance name>, if <Name> is blank.]*

Related composition: <Related composition>

Classification

The substance is not classified *[Rule: Print if the checkbox "not classified" is selected.]*

The substance is classified as follows: *[Rule: Print if either of the "Classification" fields is populated.]*

Table 23. Classification and labelling in Annex I of Directive 67/548/EEC for physicochemical properties

Endpoint	Classification	Reason for no classification	CSR section*)
Explosiveness:	<Explosiveness>	<reasonForNoClassification>	6.1
Oxidising properties:	<Oxidising properties>	<reasonForNoClassification>	6.2
Flammability:	<Flammability>	<reasonForNoClassification>	6.3
Thermal stability:	<Thermal stability>	<reasonForNoClassification>	

*) Justification for (non) classification can be found in the CSR section indicated

Table 24. Classification and labelling in Annex I of Directive 67/548/EEC for health hazards

Endpoint	Classification	Reason for no classification	CSR section*)
Acute toxicity:	<Acute toxicity>	<reasonForNoClassification>	5.2.3
Acute toxicity - irreversible damage after single exposure:	<Acute toxicity - irreversible damage after single exposure>	<reasonForNoClassification>	5.2.3
Repeated dose toxicity:	<Repeated dose toxicity>	<reasonForNoClassification>	5.6.3
Irritation / Corrosion:	<Irritation / Corrosion>	<reasonForNoClassification>	5.3.4 and 5.4.3
Sensitisation:	<Sensitisation>	<reasonForNoClassification>	5.5.3
Carcinogenicity:	<Carcinogenicity>	<reasonForNoClassification>	5.8.3
Mutagenicity - Genetic Toxicity:	<Mutagenicity - Genetic Toxicity>	<reasonForNoClassification>	5.7.3
Toxicity to reproduction - fertility:	<Toxicity to reproduction - fertility>	<reasonForNoClassification>	5.9.3
Toxicity to reproduction - development:	<Toxicity to reproduction - development>	<reasonForNoClassification>	5.9.3
Toxicity to reproduction - breastfed babies:	<Toxicity to reproduction - breastfed babies>	<reasonForNoClassification>	5.9.3

*) Justification for (non) classification can be found in the CSR section indicated

Table 25. Classification and labelling in Annex I of Directive 67/548/EEC for the environment

Endpoint	Classification	Reason for no classification	CSR section*)
Environment:	<Environment>	<reasonForNoClassification>	7.6

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Indication of danger:

<Indication of danger>

R-phrases:

<Risk phrases>

S-phrases:

<Code> (<Additional text>)

Specific concentration limits:

Concentration (%)	Classification
<Concentration range>	<Indication of danger (symbols)>.

Notes:

<Notes>

3.2.2 Self classification(s)

[IUCLID source: section 2.2 DSD - DPD; condition: if field "Status" = "67/548/EEC self classification".]

No relevant information available *[Rule: Print if none of the fields specified below is populated. Note: This default text is not printed if any field "Reason for no classification" is populated with the IUCLID default phrase "data lacking".]*

Chemical name: <Name> *[Alternatively: Substance: <Reference substance name>, if <Name> is blank.]*

Related composition: <Related composition>

Remarks: <Remarks>

Table 26. Self classification according to Directive 67/548/EEC criteria

Endpoint	Classification	Reason for no classification	CSR section*)
Explosiveness	<Explosiveness>	<Reason for no classification>	6.1
Oxidising properties	<Oxidising properties>	<Reason for no classification>	6.3
Flammability	<Flammability>	<Reason for no classification>	6.2
Thermal stability	<Thermal stability>	<Reason for no classification>	
Acute toxicity	<Acute toxicity>	<Reason for no classification>	5.2.3
Acute toxicity- irreversible damage after single exposure	<Acute toxicity - irreversible damage after single exposure>	<Reason for no classification>	5.2.3
Repeated dose toxicity	<Repeated dose toxicity>	<Reason for no classification>	5.6.3
Irritation / Corrosion	<Irritation / Corrosion>	<Reason for no classification>	5.3.4 and 5.4.3
Sensitisation	<Sensitisation>	<Reason for no classification>	5.5.3
Carcinogenicity	<Carcinogenicity>	<Reason for no classification>	5.8.3
Mutagenicity - Genetic Toxicity	<Mutagenicity - Genetic Toxicity>	<Reason for no classification>	5.7.3
Toxicity to reproduction-fertility	<Toxicity to reproduction - fertility>	<Reason for no classification>	5.9.3
Toxicity to reproduction-development	<Toxicity to reproduction - development>	<Reason for no classification>	5.9.3
Toxicity to reproduction - breastfed babies	<Toxicity to reproduction - breastfed babies>	<Reason for no classification>	5.9.3
Environment	<Environment>	<Reason for no classification>	7.6

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Indication of danger:

<Indication of danger>

R-phrases:

<Risk phrases>

S-phrases:

<Code> (<Additional text>)

Specific concentration limits:

Concentration (%)	Classification
<Concentration range>	<Indication of danger (symbols)>

Notes:

<Notes>

3.2.3. Other classification(s)

[IUCLID source: section 2.2 DSD - DPD; condition: if field "Status" = "other:" (free text) or blank.]

No relevant information available *[Rule: Print if none of the fields specified below is populated and the checkbox "not classified" is not ticked. Note: This default text is not printed if any field "Reason for no classification" is populated with the IUCLID default phrase "data lacking".*
For technical reasons this default text is not printed if any information captured from IUCLID section 2.2 is included in CSR section 3.2.1 and/or 3.2.2.]

Status: <Status> *[Alternatively: Status: >>>??? IUCLID field empty!<<<, if <Status> is blank.]*

Chemical name: <Name> *[Alternatively: Substance: <Reference substance name>, if <Name> is blank.]*

Related composition: <Related composition>

Remarks: <Remarks>

The substance is not classified *[Rule: Print if the checkbox "not classified" is selected.]*

Table 27: <Status>

Endpoint	Classification	Reason for no classification	CSR section*)
Explosiveness	<Explosiveness>	<Reason for no classification>	6.1
Oxidising properties	<Oxidising properties>	<Reason for no classification>	6.3
Flammability	<Flammability>	<Reason for no classification>	6.2
Thermal stability	<Thermal stability>	<Reason for no classification>	
Acute toxicity	<Acute toxicity>	<Reason for no classification>	5.2.3
Acute toxicity- irreversible damage after single exposure	<Acute toxicity - irreversible damage after single exposure>	<Reason for no classification>	5.2.3
Repeated dose toxicity	<Repeated dose toxicity>	<Reason for no classification>	5.6.3
Irritation / Corrosion	<Irritation / Corrosion>	<Reason for no classification>	5.3.4 and 5.4.3

Sensitisation	<Sensitisation>	<Reason for no classification>	5.5.3
Carcinogenicity	<Carcinogenicity>	<Reason for no classification>	5.8.3
Mutagenicity - Genetic Toxicity	<Mutagenicity - Genetic Toxicity>	<Reason for no classification>	5.7.3
Toxicity to reproduction-fertility	<Toxicity to reproduction - fertility>	<Reason for no classification>	5.9.3
Toxicity to reproduction-development	<Toxicity to reproduction - development>	<Reason for no classification>	5.9.3
Toxicity to reproduction - breastfed babies	<Toxicity to reproduction - breastfed babies>	<Reason for no classification>	5.9.3
Environment	<Environment>	<Reason for no classification>	7.6

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Indication of danger:

<Indication of danger>

R-phrases:

<Risk phrases>

S-phrases:

<Code> (<Additional text>)

Specific concentration limits:

Concentration (%)	**Classification**
<Concentration range>	<Indication of danger (symbols)>

Notes:

<Notes>

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways

<Discussion> *[IUCLID source: Endpoint summary 5. Environmental fate and pathways]*

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

[IUCLID source: section 5.1.2 Hydrolysis.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if none of the following kind of information is available: (i) any endpoint study record with field "Purpose flag" being populated; (ii) any record with field "Data waiving" being populated, but "Purpose flag" being blank; (iii) any record with field "Study result type" containing "experimental study planned".]*

The studies on hydrolysis are summarised in the following table:

Table 28. Studies on hydrolysis

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Estimation method (if used)>	Half-life (DT50): t1/2 (pH <pH>): <Half-life> at <Temp.>; Rate constant: <Hydrolysis rate constant>; Type: <Type> <(Remarks)> Recovery (in %): pH <pH>: <%Recovery> at <Temp., value> <Temp., unit> after <Duration> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Hydrolysis

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Hydrolysis

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.1.2 Hydrolysis.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA:

Half-life for hydrolysis: <Half-life for hydrolysis> at <Temperature> <Unit>

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

[IUCLID source: section 5.1.1 Phototransformation in air.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The studies on phototransformation in air are summarised in the following table:

Table 29. Studies on phototransformation in air

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Estimation method (if used)> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity>	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <%Degr.> after <Sampling time> (<Test condition>) Degradation rate constant: <Rate constant> for reaction with <Reaction with>*[Repeat for each record of the block.]* Quantum yield: <Quantum yield (for direct photolysis)> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Phototransformation in air
Reason: <Data waiving>
Justification: <Justification for data waiving>

Testing proposal

Information requirement: Phototransformation in air
Proposed test guideline: <Guideline>
Principles of method if other than guideline:
<Principles of method if other than guideline>
Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.1.1 Phototransformation in air.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA:

Half-life in air: <Half-life in air> <Unit>

Degradation rate constant with OH radicals: <Degradation rate constant with OH radicals> <Unit>

4.1.1.2.2. Phototransformation in water

[IUCLID source: section 5.1.3 Phototransformation in water.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The studies on phototransformation in water are summarised in the following table:

Table 30. Studies on phototransformation in water

Method	Results	Remarks	Reference
Study type: <Study type> <Guideline> <Principles of method if other than guideline> <Computational methods> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity> Sensitiser: <Type of sensitiser> (<RANGE_UNIT: Concentration of sensitiser>)	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <%Degr.> after <Sampling time> (<Test condition>) Quantum yield: <Quantum yield (for direct photolysis)> Rate constant: <Rate constant> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Phototransformation in water

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Phototransformation in water

Proposed test guideline: <Guideline>

Planned study type: <Study type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.1.3 Phototransformation in water.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA:

Half-life in water: <Half-life in water> <Unit>

4.1.1.2.3. Phototransformation in soil

[IUCLID source: section 5.1.4 Phototransformation in soil.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The studies on phototransformation in soil are summarised in the following table:

Table 31. Studies on phototransformation in soil

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline> <Computational methods> Light source: <Light source> Light spectrum: <Light spectrum> Rel. light intensity: <Rel. light intensity> Details on soil: <Details on soil>	Spectrum of substance: <Parameter>: <Value> <Unit> (<Remarks>) Half-life (DT50): <DT50> (<Test condition>) % Degradation: <%Degr.> after <Sampling time> (<Test condition>) Quantum yield: <Quantum yield (for direct photolysis)> Transformation products: <Transformation products>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Phototransformation in soil

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Phototransformation in soil

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.1.4 Phototransformation in soil.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA:

Half-life in soil: <Half-life in soil> <Unit>

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

[IUCLID source: section 5.2.1 Biodegradation in water: screening tests.
Sort rule in table: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study". (II.) Field "Oxygen conditions" = (1) "aerobic"; (2) anaerobic".]

No relevant information available *[Rule: Print if applicable.]*

The studies on biodegradation in water (screening tests) are summarised in the following table:

Table 32. Screening tests for biodegradation in water

Method	Results	Remarks	Reference
Test type: <Test type> <Inoculum or test system> (<Oxygen conditions>*) [If "Oxygen conditions = anaerobic" and "Inoculum" <> "anaerobic ...".]* <Guideline> <Principles of method if other than guideline>	<Interpretation of results> % Degradation of test substance: <% Degradation of test substance> after <Sampling time> (<Parameter>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Biodegradation in water: screening test (<Test type>)

Proposed test guideline: <Guideline>

Test system: <Inoculum or test system> (<Oxygen conditions>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

4.1.2.1.2. Simulation tests (water and sediments)

[IUCLID source: section 5.2.2 Biodegradation in water and sediment: simulation tests.
Sort rule in table: (I.) Field "Inoculum or test system" = (1) "natural water"; (2) natural water / sediment"; (3) "natural sediment". (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The studies on biodegradation in water and sediments (simulation tests) are summarised in the following table:

Table 33. Simulation tests for biodegradation in water and sediment

Method	Results	Remarks	Reference
Test system: <Inoculum or test system> (<Oxygen conditions>) <Guideline> <Principles of method if other than guideline>	Half-life (DT50): <Half-life> in <Compartment> at <Temperature> % Degradation of test substance: <% Degradation of test substance> after <Sampling time> (<Parameter>) (<Remarks>) Mineralization rate: <Mineralization rate> <Unit> Transformation products: <Transformation products> *[Rule: Print if "no" or "not measured".]* Transformation products: <Identity>*[Rule: Print all transformation products in separate lines.]*	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Simulation testing for biodegradation in water and sediment

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Simulation testing on ultimate degradation in surface water
[Rule: Print if field "Inoculum or test system" is not "natural sediment".

Information requirement: Sediment simulation testing
[Rule: Print of field "Inoculum or test system" = "natural sediment.]

Proposed test guideline: <Guideline>

Test system: <Inoculum or test system> (<Oxygen conditions>)

Source and properties of surface water: <Details on source and properties of surface water>

Source and properties of sediment: <Details on source and properties of sediment>

Study design: <Details on study design>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

Discussion (screening testing) *[IUCLID source: Endpoint summary 5.2.1 Biodegradation in water: screening tests.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA: Biodegradation in water: <Biodegradation in water>

Discussion (simulation testing) *[IUCLID source: Endpoint summary 5.2.2 Biodegradation in water and sediment: simulation tests.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA:

Half-life in water: <Half-life in water> <Unit> at <Temperature> <Unit>

Half-life in sediment: <Half-life in sediment> <Unit>at <Temperature> <Unit>

4.1.2.2. Biodegradation in soil

[IUCLID source: section 5.2.3 Biodegradation in soil.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The test results are summarised in the following table:

Table 34. Simulation tests for biodegradation in soil

Method	Results	Remarks	Reference
Test type: <Test type> Soil type: <Soil type> (<Soil No.>) <Guideline> <Principles of method if other than guideline>	Half-life (DT50): <Half-life> (<Soil No.>) (<Remarks>) % Degradation of test substance: <% Degradation of test substance> after <Sampling time> (<Parameter>) (<Soil No.>) Evaporation of parent compound: < Evaporation of parent compound> Volatile metabolites: <Volatile metabolites> Residues: < Residues> Transformation products: <Transformation products>*[Rule: Print if "no" or "not measured".]* Transformation products: <Identity>*[Rule: Print all transformation products in separate lines.]*	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Soil simulation testing

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal *[IUCLID source: Endpoint summary 5.2.3 Biodegradation in soil]*

Information requirement: Soil simulation testing

Proposed test guideline: <Guideline>

Soil type: <Soil type>

Study design: <Details on experimental conditions>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.2.3 Endpoint summary Biodegradation in soil.]*

<Discussion>

The following information is taken into account for any hazard / risk / persistency assessment:

<Short description of key information>

Value used for CSA:

Half-life in soil: <Half-life in soil> <Unit> at <Temperature> <Unit>

4.1.3. Summary and discussion of degradation

Abiotic degradation

<Discussion> *[IUCLID source: Endpoint summary 5.1 Stability.]*

Biotic degradation

<Discussion> *[IUCLID source: Endpoint summary 5.2 Biodegradation.]*

4.2. Environmental distribution

4.2.1. Adsorption/desorption

[IUCLID source: section 5.4.1 Adsorption / desorption.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The studies on adsorption/desorption are summarised in the following table:

Table 35. Studies on adsorption/desorption

Method	Results	Remarks	Reference
Study type: <Study type> (<Media>) <Type of method> <Guideline> <Principles of method if other than guideline>	Adsorption coefficient <Type>: <Value> at <Temperature> <Unit> (Org. C (%): <Org. carbon>) (<Remarks>) Other adsorption coefficients: <Type>: <Value> at <Temperature> <Unit> (<Remarks>) Mass balance (in %) at end of adsorption phase:	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

	<% adsorption> after <Duration> (<Sample No.>) Mass balance (in %) at end of desorption phase: <% desorption> after <Duration> (<Sample No.>) Transformation products: <Transformation products>*[Rule: Print if "no" or "not measured".]* Transformation products: <Identity>*[Rule: Print all transformation products in separate lines.]*		

Data waiving

Information requirement: Adsorption/desorption

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Adsorption/desorption

Proposed test guideline: <Guideline>

Study type: <Study type> <(Media)>

Type of method: <Type of method>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.4.1 Adsorption / desorption.]*

<Discussion>

The following information is taken into account for any environmental exposure assessment:

<Short description of key information>

Value used for CSA:

Koc at 20°C: <Koc at 20°C>

Log Koc at 20°C: <Log Koc at 20°C>

Other adsorption coefficients:

<Type>: <Value> <Unit> at <Temperature> <Unit>

4.2.2. Volatilisation

[IUCLID source: section 5.4.2 Henry's Law constant.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The studies on volatilisation are summarised in the following table:

Table 36. Studies on volatilisation

Method	Results	Remarks	Reference
<Principles of method if other than guideline> <Details on methods>	Henry's Law constant H: <H> at <Temp. (°C)> °C and <Atm. press.> <Atm. press., unit> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Volatilisation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Volatilisation

Proposed test guideline: <Guideline>
Details on methods: <Details on methods>

Principles of method if other than guideline:
<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 5.4.2 Henry's Law constant.]*

<Discussion>

The following information is taken into account for any environmental exposure assessment:

<Short description of key information>

Value used for CSA: Henry's law constant (H): <Henry's law constant (H)> (in Pa m³/mol or dimensionless) at <Temperature> <Unit>

4.2.3. Distribution modelling

[IUCLID source: section 5.4.3 Distribution modelling.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The data from distribution modelling studies are summarised in the following table:

Table 37. Distribution modelling studies

Method	Results	Remarks	Reference
Media: <Media> <Model> Calculation programme: <Calculation programme> Input data: <Test substance input data>	Percent distribution in media: Air (%): <Air (%)> Water (%): <Water (%)> Soil (%): <Soil (%)> Sediment (%): <Sediment (%)> Susp. sediment (%): <Susp. sediment (%)> Biota (%): <Biota (%)> Aerosol (%): <Aerosol (%)> Other distribution results: <Other distribution results>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Distribution modelling

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Distribution modelling

Model: <Model>

Media: <Media>

Planned study period: <Study period>

4.2.4. Summary and discussion of environmental distribution

<Discussion> *[IUCLID source: Endpoint summary 5.4 Transport and distribution.]*

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

[IUCLID source: section 5.3.1 Bioaccumulation: aquatic / sediment.
Sort rule: (I.) Field "Route of exposure" = (1) "aqueous"; (2) "sediment"; (3) "feed"; (4) "other"; (5) empty; (II.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty;(III.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"]

No relevant information available *[Rule: Print if applicable.]*

The studies on aquatic bioaccumulation are summarised in the following table:

Table 38. Studies on aquatic bioaccumulation

Method	Results	Remarks	Reference
<Test organisms (species)> <Route of exposure> (<Water media type>) <Test type> Sediment type: <Type of sediment (if sediment study)> Total exposure / uptake duration: <Total exposure / uptake duration> <Unit> Total depuration duration: <Total depuration duration> <Unit> Details on estimation of bioconcentration: <Details on estimation of bioconcentration> *[Print only if field "Details on estimation of bioconcentration" is populated.]* <Guideline> <Principles of method if other than guideline>	<Bioaccumulation factor_Type>: <Bioaccumulation factor> <Unit> (<Basis>) (<Time of plateau: <Time of plateau> (<Calculation basis>) (<Remarks)>) Elimination: <Elimination>; <Endpoint>: <Depuration time (DT)> Lipid content: <Lipid content> (<Time point>)> (<Remarks>) Transformation products: <Metabolites>	<Reliability> <Purpose Flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Aquatic bioaccumulation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Aquatic bioaccumulation

Proposed test guideline: <Guideline>

Species: <Test organisms (species)>

Compartment / route: <Route of exposure> (<(Water media type)>

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

4.3.2. Terrestrial bioaccumulation

[IUCLID source: section 5.3.2 Bioaccumulation: terrestrial.]
Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study".

No relevant information available *[Rule: Print if applicable.]*

The results of terrestrial bioaccumulation studies are summarised in the following table:

Table 39: Studies on terrestrial bioaccumulation

Method	Results	Remarks	Reference

<Test organisms (species)> <Guideline> <Principles of method if other than guideline>	<Bioaccumulation factor_Type>: <Bioaccumulation factor> <Unit> (<Basis>) (<Time of plateau: <Time of plateau>) (<Calculation basis>) (<Remarks)>) Elimination: <Elimination>; <Endpoint>: <Depuration time (DT)> Lipid content: <Lipid content> (<Time point>)>) (<Remarks>) Transformation products: <Metabolites>	<Reliability> <Purpose Flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Terrestrial bioaccumulation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Terrestrial bioaccumulation

Proposed test guideline: <Guideline>

Species: <Test organisms (species)>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

4.3.3. Summary and discussion of bioaccumulation

<Discussion> *[IUCLID source: Endpoint summary 5.3 Bioaccumulation.]*

Aquatic bioaccumulation *[IUCLID source: Endpoint summary 5.3.1 Bioaccumulation: aquatic / sediment.]*

<Discussion>

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

<Short description of key information>

Value used for CSA: BCF: <BCF (aquatic species)> <Unit>

Terrestrial bioaccumulation *[IUCLID source: Endpoint summary 5.3.2 Bioaccumulation: terrestrial.]*

<Discussion>

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

<Short description of key information>

Value used for CSA: BCF: <BCF (terrestrial species)> <Unit>

4.4. Secondary poisoning

[Rule: If "Hazard assessment conclusion" = "No potential for bioaccumulation" or "No potential to cause toxic effects if accumulated (in higher organisms) via the food chain", the following default statement is inserted:]

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.6 "PNEC derivation and other hazard conclusions)").

[Rule: If "Hazard assessment conclusion" = "No or insufficient data available at present" or "No data available: testing technically not feasible" or blank, the following default statement is inserted:]

Based on the available information the bioaccumulation potential cannot be judged (see CSR chapter 7.6 "PNEC derivation and other hazard conclusions").

[Rule: If a PNEC oral is provided, the following default statements are inserted:]

The hazard assessment conclusion for secondary poisoning (PNECoral) is <PNEC oral> <Unit> (see CSR chapter 7.6 "PNEC derivation and other hazard conclusions").

Interpretation of the available data with regard to the potential to bio-accumulate in the food chain:

>>>NOTE (please delete this instruction): As appropriate enter relevant information manually.<<<<

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

Summary and discussion of human information*[Rule: This subheading and the pieces of information below are only printed if "Short description of key information" and/or "Discussion" are populated in IUCLID source section 7.10 Endpoint summary "Exposure related observations in humans".]*

(Note: The following summary has been extracted from the endpoint summary of IUCLID section 7.10 Exposure related observations in humans. It may be appropriate to manually move or copy relevant part(s) to the "Summary and discussion" part of the corresponding CSR chapter(s).)

Key information:

<Short description of key information> *[IUCLID source: section 7.10 Endpoint summary "Exposure related observations in humans".]*

Discussion:

<Discussion> *[IUCLID source: section 7.10 Endpoint summary "Exposure related observations in humans".]*

5.1.1. Non-human information

No relevant information available *[Rule: Print if applicable.]*

The results of studies on absorption, metabolism, distribution and elimination are summarised in the following table:

Table 40. Studies on absorption, metabolism, distribution and elimination

Method	Results	Remarks	Reference
[IUCLID source: section 7.1.1 Basic toxicokinetics. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
in vitro study *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) <Sex> <Route of administration> Exposure regime: <Duration and frequency of treatment Doses/conc.: <Doses / concentrations> <Guideline> <Principles of method if other than guideline>	Main ADME results: <Type>: <Text>) Transfer (<Transfer type>): <Transfer type>: <Observation> (Test No.: <Test No.>) Toxicokinetic parameters: <Toxicokinetic parameters> (Test No.: <Test No.>) Absorption: <Details on absorption> *[Rule: Print only if field "Type (Main ADME results)" does not contain "absorption"]* Distribution: <Details on distribution in tissues> *[Rule: Print only if field "Type (Main ADME results)" does not contain "distribution"]* Excretion: <Details on excretion> *[Rule: Print only if field "Type (Main ADME results)" does not contain "excretion"]* Metabolites identified: <Metabolites identified> Details on metabolites: <Details on	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

	metabolites> Evaluation of results: <Interpretation of results>		
[IUCLID source: section 7.1.2 Dermal absorption. Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Dermal absorption study in vitro *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) <Sex> Coverage (dermal absorption study): <Type of coverage> <Duration of exposure> Doses/conc.: <Doses / concentrations> <Details on in vitro test system (if applicable)> <Guideline> <Principles of method if other than guideline>	<Absorption in different matrices> Total recovery: <Total recovery> Percutaneous absorption rate: <Absorption (%)> % at <Time point> (<Dose>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Basic toxicokinetics *[If source is IUCLID section 7.1.1.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Information requirement: Dermal absorption *[If source is IUCLID section 7.1.2.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Basic toxicokinetics *[If source is IUCLID section 7.1.1.]*

Proposed test guideline: <Guideline>

Type of method: <Type of method>

Route of administration: <Route of administration>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Information requirement: Dermal absorption *[If source is IUCLID section 7.1.2.]*

Proposed test guideline: <Guideline>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.1.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 41. Exposure-related observations on basic toxicokinetics and/or dermal absorption in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "basic toxicokinetics" or "dermal absorption". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4)*			

"disregarded study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.1.3. Summary and discussion of toxicokinetics

<Discussion> *[IUCLID source: Endpoint summary 7.1 Toxicokinetics, metabolism and distribution.]*

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA:

Bioaccumulation potential: <Bioaccumulation potential>

Absorption rate - oral (%): <Absorption rate - oral (%)>

Absorption rate - dermal (%): <Absorption rate - dermal (%)>

Absorption rate - inhalation (%): <Absorption rate - inhalation (%)>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

[IUCLID source: section 7.2.1 Acute toxicity: oral.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".
Rule for multiple "Effect levels": Capture only LD50 values or, if not available, any other.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 42. Studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules*	<Author> <Year>

		in introductory part.] Form: <Test material form> [*If field is populated]*	

Data waiving

Information requirement: Acute toxicity after oral administration

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Acute toxicity after oral administration

Proposed test guideline: <Guideline>

Test type: <Test type> (<Route of administration>)

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.2.1.2. Acute toxicity: inhalation

[IUCLID source: section 7.2.2 Acute toxicity: inhalation.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".
Rule for multiple "Effect levels": Capture only LC50 values or, if not available, any other.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on acute toxicity after inhalation exposure are summarised in the following table:

Table 43. Studies on acute toxicity after inhalation exposure

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Exp. duration>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Acute toxicity after inhalation exposure

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Acute toxicity after inhalation exposure

Proposed test guideline: <Guideline>

Test type: <Test type> (<Route of administration>)

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.2.1.3. Acute toxicity: dermal

[IUCLID source: section 7.2.3 Acute toxicity: dermal.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".
Rule for multiple "Effect levels": Capture only LD50 values or, if not available, any other.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on acute toxicity after dermal administration are summarised in the following table:

Table 44. Studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> Coverage: <Type of coverage> Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Acute toxicity after dermal administration

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Acute toxicity after dermal administration

Proposed test guideline: <Guideline>

Test type: <Test type> (Type of coverage: <Type of coverage>)

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.2.1.4. Acute toxicity: other routes

[IUCLID source: section 7.2.4 Acute toxicity: other routes.
Sort rule in table: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on acute toxicity (other routes) are summarised in the following table:

Table 45. Studies on acute toxicity (other routes)

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Acute toxicity (other routes)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Acute toxicity (other routes)

Proposed test guideline: <Guideline>

Route of administration: <Route of administration>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.2.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 46. Exposure-related observations on acute toxicity in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "acute toxicity:". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "acute toxicity:".*			

Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "acute toxicity:".* *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "acute toxicity:".* *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.2.3. Summary and discussion of acute toxicity

[IUCLID source: Endpoint summary 7.2 Acute toxicity.]

<Discussion>

<u>The following information is taken into account for any hazard / risk assessment:</u>

<Short description of key information>

Value used for CSA:*[Rule: Print item if an Effect level is provided and/or "Endpoint conclusion" is populated.]*

Acute oral toxicity: <Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level unit>
e.g.
Acute oral toxicity: No adverse effect observed (LD50 >2000 mg/kg bw)

or
Acute oral toxicity: No study available

Acute dermal toxicity: <Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level unit>)

Acute inhalation toxicity: <Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level unit>)

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

[IUCLID source: section 7.3.1 Skin irritation / corrosion.
Rule: Insert if field "Interpretation of results" <> "corrosive", "highly corrosive*", "Category 1 (corrosive)*", "Category 1A (corrosive)*", "Category 1B (corrosive)*", "Category 1C (corrosive)*", "Category 1*" .*
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "primary dermal irritation index (PDII)"; (3) "erythema score"; (4) "edema score".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on skin irritation are summarised in the following table:

Table 47. Studies on skin irritation

Method	Results	Remarks	Reference
in vitro study *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) Coverage: <Type of coverage> (<Preparation of test site>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Primary dermal irritation index (PDII): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Erythema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Edema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

	<Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)		

Studies with results indicating corrosivity to the skin are summarised in section 5.4 Corrosivity. *[Insert if field "Interpretation of results" = "corrosive*", "highly corrosive*", "Category 1 (corrosive)*", "Category 1A (corrosive)*", "Category 1B (corrosive)*", "Category 1C (corrosive)*", "Category 1*".]*

Data waiving

Information requirement: Skin irritation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Skin irritation

Proposed test guideline: <Guideline>

Type of method: <Type of method> (Type of coverage: <Type of coverage>)

Species: <Species> (<Strain>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.3.1.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 48. Exposure-related observations on skin irritation in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "skin irritation / corrosion". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "skin irritation / corrosion". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]*	<Author> <Year>

Endpoint addressed: <Endpoint addressed>		Form: <Test material form> [*If field is populated]*	
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "skin irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "skin irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.3.2. Eye

5.3.2.1. Non-human information

[IUCLID source: section 7.3.2 Eye irritation.
Rule: Insert if field "Interpretation of results" <> "corrosive", "highly corrosive*", "Category 1*" or "Category I*".*
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "Maximum mean total score (MMTS)"; (3) "cornea score"; (4) "iris score"; (5) "conjunctivae score"; (6) "chemosis score".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on eye irritation are summarised in the following table:

Table 49. Studies on eye irritation

Method	Results	Remarks	Reference
in vitro study *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) Vehicle: <Vehicle> <Guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Maximum mean total score (MMTS):	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules*	<Author> <Year>

<Principles of method if other than guideline>	<Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Cornea score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Iris score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Conjunctivae score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Chemosis score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) <Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	*in introductory part.]* Form: <Test material form> [*If field is populated]*	

Studies with results indicating corrosivity to the eye are summarised in section 5.4 Corrosivity.. *[Insert if field "Interpretation of results" = "corrosive*", "highly corrosive*", "Category 1*" or "Category I*".]*

Data waiving

Information requirement: Eye irritation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Eye irritation

Proposed test guideline: <Guideline>

Type of method: <Type of method>

Species: <Species> (<Strain>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.3.2.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 50. Exposure-related observations on eye irritation in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "eye irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "eye irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "eye irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "eye irritation / corrosion". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material	<Author> <Year>

		form> [*If field is populated]*	

5.3.3. Respiratory tract

5.3.3.1. Non-human information

5.3.3.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 51. Exposure-related observations on respiratory irritation in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "respiratory irritation / corrosion". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "respiratory irritation / corrosion". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "respiratory irritation / corrosion". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is*	<Author> <Year>

		populated]	
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "respiratory irritation / corrosion". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.3.4. Summary and discussion of irritation

[IUCLID source: Endpoint summary 7.3 Irritation / corrosion.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA:

Skin irritation / corrosion: <Endpoint conclusion> (<Effect level value>)
e.g.
Skin irritation / corrosion: Adverse effect observed (slightly irritating)

Eye irritation: <Endpoint conclusion> (<Effect level value>)

Respiratory irritation: <Endpoint conclusion> (<Effect level value>)

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

5.4. Corrosivity

5.4.1. Non-human information

[IUCLID source: sections 7.3.1 Skin irritation / corrosion.
Rule: Insert if field "Interpretation of results" = "corrosive", "highly corrosive*", "Category 1 (corrosive)*", "Category 1A (corrosive)*", "Category 1B (corrosive)*", "Category 1C (corrosive)*", "Category 1*".*
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "primary dermal irritation index (PDII)"; (3) "erythema score"; (4) "edema score".]

[IUCLID source: section 7.3.2 Eye irritation.
Rule: Insert if field "Interpretation of results" = "corrosive", "highly corrosive*", "Category 1*" or "Category I*".*
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Sort rule for multiple "Irritation parameter": Field "Irritation parameter" = (1) "overall irritation score"; (2) "Maximum mean total score (MMTS)"; (3) "cornea score"; (4) "iris score"; (5) "conjunctivae score"; (6) "chemosis score".]

No relevant information available *[Rule: Print if no relevant endpoint study records (i.e. field "Purpose flag" being populated) are available in the source sections 7.3.1 and 7.3.2.]*

The results of studies on skin and eye irritation related to corrosivity are summarised in the following table:

Table 52. Studies on skin and eye irritation related to corrosivity

Method	**Results**	**Remarks**	**Reference**
[IUCLID source: section 7.3.1 Skin irritation / corrosion.]			
Tissue studied: skin in vitro study *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) Coverage: <Type of coverage> (<Preparation of test site>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Primary dermal irritation index (PDII): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Erythema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Edema score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) <Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.3.2 Eye irritation.]			
Tissue studied: eye in vitro study *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Overall irritation score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Maximum mean total score (MMTS): <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Cornea score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Iris score: <Score> of max. <Max. score>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

	(<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Conjunctivae score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) Chemosis score: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>) <Irritation parameter>: <Score> of max. <Max. score> (<Basis>) (Time point: <Time point>) (<Reversibility>) (<Remarks>)		

5.4.2. Human information

5.4.3. Summary and discussion of corrosion

The studies with results indicating corrosivity are discussed in section 5.3.4 Summary and discussion of irritation. *[Insert if field "Interpretation of results" = "corrosive*", "highly corrosive*", "Category 1 (corrosive)*", "Category 1A (corrosive)*", "Category 1B (corrosive)*", "Category 1C (corrosive)*", "Category I*", "Category 1*".]*

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

[IUCLID source: sections 7.3.1 Skin irritation / corrosion.
Sort rule in tables: (I.) Field "Type of study" = (1) "Mouse local lymphnode assay (LLNA)"; (2) <> "Mouse local lymphnode assay (LLNA)"; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on skin sensitisation are summarised in the following table:

Table 53. Studies on skin sensitisation

Method	Results	Remarks	Reference
in vitro study *[Rule: If field "Type of method" = "in vitro".]* <Species> (<Strain>) <Sex> Local lymph node assay *[Rule: If "Type of study" = "LLNA".]* <Type of study> *[Rule: If "Type of study" <> "LLNA".]* Induction: <Route of induction exposure>*[Rule: If "Type of study" <> "LLNA".]* Challenge: <Route of challenge exposure>*[Rule: If "Type of study" <> "LLNA".]* Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> Stimulation index: <Stimulation index> *[Rule: If "Type of study" = "LLNA".]* No. with positive reactions:*[Rule: If "Type of study" <> "LLNA".]* <Reading>: <No. with + reactions> out of <Total no. in group> (<Group>; <Hours after challenge> h after chall.; dose: <Dose level>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Skin sensitisation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Skin sensitisation

Proposed test guideline: <Guideline>

Type of study: <Type of study> (<Type of method>)

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.5.1.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 54. Exposure-related observations on skin sensitisation in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.4 Sensitisation data (humans), if "Type of sensitisation studied" = "skin". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> Type of population: <Type of population> Subjects: <Subjects>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "skin sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "skin sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "skin sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is*	<Author> <Year>

		populated]	
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "skin sensitisation". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.5.2. Respiratory system

5.5.2.1. Non-human information

[IUCLID source: section 7.4.2 Respiratory sensitisation.
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on respiratory sensitisation are summarised in the following table:

Table 55. Studies on respiratory sensitisation

Method	Results	Remarks	Reference
in vitro study *[If field "Type of method" = "in vitro".]* <Species> (<Strain>) <Sex> Induction: <Route of induction exposure> Challenge: <Route of challenge exposure> Vehicle: <Vehicle> <Guideline> <Principles of method if other than guideline>	<Interpretation of results> <Results>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Respiratory sensitisation

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal:

Information requirement: Respiratory sensitisation

Proposed test guideline: <Guideline>

Type of method: <Type of method>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.5.2.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 56. Exposure-related observations on respiratory sensitisation in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.4 Sensitisation data (humans), if "Type of sensitisation studied" = "respiratory". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> Type of population: <Type of population> Subjects: <Subjects>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "respiratory sensitisation". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study	<Results of examinations>	<Reliability>	<Author> <Year>

type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	Outcome of incidence: <Outcome of incidence>	<Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "respiratory sensitisation". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.5.3. Summary and discussion of sensitisation

Skin sensitisation *[IUCLID source: Endpoint summary 7.4 Sensitisation: Skin sensitisation.]*

<Skin sensitisation, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Skin sensitisation, Short description of key information>

Value used for CSA: <Endpoint conclusion>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

Respiratory sensitisation *[IUCLID source: Endpoint summary 7.4 Sensitisation: Respiratory sensitisation.]*

<Respiratory sensitisation, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Respiratory sensitisation, Short description of key information>

Value used for CSA: <Endpoint conclusion>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

Justification for classification or non classification *[IUCLID source: Endpoint summary 7.4 Sensitisation.*

Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]

<Justification for classification or non-classification>

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

[IUCLID source: section 7.5.1 Repeated dose toxicity: oral.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".
Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL identified"; (2) "NOAEL"; (3) "NOEL"; (4) "LOAEL"; (5) "LOEL"; (6) "BMD05"; (7) "BMD10" ; (8) "BMD:" ; (9) any other or empty.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies are summarised in the following table:

Table 57. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: short-term toxicity study (28 days) (oral) / sub-chronic toxicity study (90 days) (oral) / <Test type> (oral) *[If "Test type" = "subacute" / = "subchronic" / <> "subacute" or "subchronic", respectively.]*

Information requirement: Repeated dose toxicity after oral administration *[If "Test type" is empty.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: short-term toxicity study (28 days) (oral) / sub-chronic toxicity study (90 days) (oral) / chronic toxicity study (oral) <Test type> (oral) *[If "Test type" = "subacute" / = "subchronic" / = "chronic" / <> "subacute" or "subchronic" or "chronic", e.g.*
***Information requirement**: sub-chronic toxicity study (90 days) (oral)]*

Information requirement: Repeated dose toxicity after oral administration *[If "Test type" is empty.]*

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.6.1.2. Repeated dose toxicity: inhalation

[IUCLID source: section 7.5.3 Repeated dose toxicity: inhalation.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".
Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL/C identified"; (2) "NOAEL/C"; (3) "NOEL/C"; (4) "LOAEL/C"; (5) "LOEL/C"; (6) "BMD/C05"; (7) "BMD/C10" ; (8) "BMD/C:" ; (9) any other or empty.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies are summarised in the following table:

Table 58. Studies on repeated dose toxicity after inhalation exposure

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) (<Type of inhalation exposure>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: short-term toxicity study (28 days) (inhalation) / sub-chronic toxicity study (90 days) (inhalation) / <Test type> (inhalation) *[If <Test type> = "subacute" / = "subchronic" / <> "subacute" or "subchronic", respectively.]*

Information requirement: Repeated dose toxicity after inhalation exposure *[If "Test type" is empty.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: short-term toxicity study (28 days) (inhalation) / sub-chronic toxicity study (90 days) (inhalation) / chronic toxicity study (inhalation) <Test type> (inhalation) *[If <Test type> = "subacute" / = "subchronic" / = "chronic" / <> "subacute" or "subchronic" or "chronic", e.g.*
Information requirement*: sub-chronic toxicity study (90 days) (oral)]*

Information requirement: Repeated dose toxicity after inhalation exposure *[If "Test type" is empty.]*

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.6.1.3. Repeated dose toxicity: dermal

[IUCLID source: section 7.5.2 Repeated dose toxicity: dermal.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) <> "rat".
Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL identified"; (2) "NOAEL"; (3) "NOEL"; (4) "LOAEL"; (5) "LOEL"; (6) "BMD05"; (7) "BMD10" ; (8) "BMD:" ; (9) any other or empty.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies are summarised in the following table:

Table 59. Studies on repeated dose toxicity after dermal administration

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> Coverage: <Type of coverage> <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: short-term toxicity study (28 days) (dermal) / sub-chronic toxicity study (90 days) (dermal) / <Test type> (dermal) *[If <Test type> = "subacute" / = "subchronic" / <> "subacute" or "subchronic", respectively.]*

Information requirement: Repeated dose toxicity after dermal administration *[If "Test type" is empty.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: short-term toxicity study (28 days) (dermal) / sub-chronic toxicity study (90 days) (dermal) / chronic toxicity study (dermal) <Test type> (dermal) *[If <Test type> = "subacute" / = "subchronic" / = "chronic" / <> "subacute" or "subchronic" or "chronic", e.g.*
Information requirement*: sub-chronic toxicity study (90 days) (dermal)]*

Information requirement: Repeated dose toxicity after dermal administration *[If "Test type" is empty.]*

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.6.1.4. Repeated dose toxicity: other routes

[IUCLID source: section 7.5.4 Repeated dose toxicity: other routes.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) <>"rat".
Sort rule for multiple "Effect levels": Field "Endpoint" = (1) "no NOAEL/C identified"; (2) "NOAEL/C"; (3) "NOEL/C"; (4) "LOAEL/C"; (5) "LOEL/C"; (6) "BMD/C05"; (7) "BMD/C10" ; (8) "BMD/C:" ; (9) any other or empty.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on repeated dose toxicity (other routes) are summarised in the following table:

Table 60. Studies on repeated dose toxicity (other routes)

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> (<Route of administration>) <Doses / concentrations> Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Repeated dose toxicity (<Test type>) (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Repeated dose toxicity (<Test type>) (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.6.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 61. Exposure-related observations on repeated dose toxicity in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "repeated dose toxicity:". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "repeated dose toxicity:". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "repeated dose toxicity:". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "repeated dose toxicity:". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed:	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]*	<Author> <Year>

<Endpoint addressed>		Form: <Test material form> [*If field is populated]*	

5.6.3. Summary and discussion of repeated dose toxicity

[IUCLID source: Endpoint summary 7.5 Repeated dose toxicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA (via oral route - systemic effects):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Value used for CSA (dermal - local effects):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Value used for CSA (inhalation - systemic effects):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Value used for CSA (inhalation - local effects):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

[IUCLID source: section 7.6.1 Genetic toxicity in vitro.
Sort rule in tables: (I.) Field "Type of genotoxicity" = (1) "gene mutation"; (2) = "chromosome aberration"; (3) = "DNA damage and/or repair"; (4) ="genome mutation"; (5) = "other:" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of in vitro genotoxicity studies are summarised in the following table:

Table 62. In vitro genotoxicity studies

Method	Results	Remarks	Reference
<Type of study> (<Type of genotoxicity>) <Species/strain> (Met. act.: <Metabolic activation> Test concentrations: <Test concentrations> Positive control substance(s): <Positive control substances> [Rule: Print multiple values of each available block of fields separated by semi-colon. <Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> Test results: <Genotoxicity> for <Species/strain> (<Test system>); met. act.: <Metabolic activation>; cytotoxicity: <Cytotoxicity>; vehicle controls valid: <vehicle controls valid>; negative controls valid: <negative controls valid>; positive controls valid: <positive controls valid> *[Rule: Prompts are only printed if the corresponding fields are populated. The following phrases are ignored: "no data", "not determined", "not examined", "not applicable" and "other:".]*	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: In vitro genotoxicity: <Type of study> (<Type of genotoxicity>) *[Rule: If "Type of study" is populated and does not start with "in vitro"]*

Information requirement: In vitro genotoxicity (<Type of genotoxicity>) *[Rule: If "Type of study" is empty]*

Information requirement: In vitro genotoxicity: <Type of study> (<Type of genotoxicity>) *[Rule: If "Type of study" starts with "in vitro"]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: In vitro genotoxicity: <Type of study> (<Type of genotoxicity>) *[Rule: If "Type of study" is populated and does not start with "in vitro"]*

Information requirement: In vitro genotoxicity (<Type of genotoxicity>) *[Rule: If "Type of study" is empty]*

Information requirement: In vitro genotoxicity: <Type of study> (<Type of genotoxicity>) *[Rule: If "Type of study" starts with "in vitro"]*

Proposed test guideline: <Guideline>

Species/strain: <Species/strain> *[repeatable field]*

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.7.1.2. In vivo data

[IUCLID source: section 7.6.2 Genetic toxicity in vivo.
Sort rule in tables: (I.) Field "Type of genotoxicity" = (1) "gene mutation"; (2) = "chromosome aberration"; (3) = "DNA damage and/or repair"; (4) ="genome mutation"; (5) = "other:" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of in vivo genotoxicitystudies are summarised in the following table:

Table 63. In vivo genotoxicity studies

Method	Results	Remarks	Reference
<Type of study> (<Type of genotoxicity>) <Species> (<Strain>) <Sex> <Route of administration> Doses: <Doses / concentrations> Positive control substance(s): <Positive control substance> *[Rule: Print multiline text field if populated]* <Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> Genotoxicity: <Genotoxicity> (<Sex>); toxicity: <Toxicity>; vehicle controls valid: <vehicle controls valid>; negative controls valid: <negative controls valid>; positive controls valid: <positive controls valid> *[Rule: Prompts are only printed if the corresponding fields are populated. The following phrases are ignored: "no data", "not determined", "not examined", "not applicable" and "other:".]*	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: In vivo genotoxicity: <Type of study> (<Route of administration>) (<Type of genotoxicity>) *[Rule: If "Type of study" is populated]*

Information requirement: In vivo genotoxicity (<Type of genotoxicity>) *[Rule: If "Type of study" is empty]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: In vivo genotoxicity: <Type of study> (<Route of administration>) (<Type of genotoxicity>) *[Rule: If "Type of study" is populated]*

Information requirement: In vivo genotoxicity (<Type of genotoxicity>) *[Rule: If "Type of study" is empty]*

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.7.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 64. Exposure-related observations genetic toxicity in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "genetic toxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is*	<Author> <Year>

		populated]	

5.7.3. Summary and discussion of mutagenicity

[IUCLID source: Endpoint summary 7.6 Genetic toxicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA: Genetic toxicity: <Endpoint conclusion>

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and field "Endpoint conclusion" contains either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" = "oral: ...").
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".
Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on carcinogenicity after oral administration are summarised in the following table:

Table 65. Studies on carcinogenicity after oral administration

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> *[If "oral:*", but <> "oral: unspecified"]* <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Carcinogenicity after oral administration

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Carcinogenicity after oral administration (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.8.1.2. Carcinogenicity: inhalation

[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" = "inhalation: ..."). Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog". Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on carcinogenicity after inhalation exposure are summarised in the following table:

Table 66. Studies on carcinogenicity after inhalation exposure

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Route of administration> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Carcinogenicity after inhalation exposure

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Carcinogenicity after inhalation exposure (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.8.1.3. Carcinogenicity: dermal

[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" = "dermal").
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".
Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on carcinogenicity after dermal administration are summarised in the following table:

Table 67. Studies on carcinogenicity after dermal administration

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects observed in any test group: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Carcinogenicity after dermal administration

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Carcinogenicity after dermal administration

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.8.1.4. Carcinogenicity: other routes

[IUCLID source: section 7.7 Carcinogenicity (if field "Route of administration" does not contain "oral: gavage","oral: capsule","oral: feed","oral: drinking water","oral: unspecified","inhalation: gas","inhalation: aerosol","inhalation: dust","inhalation: vapour","inhalation","dermal".
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "mouse"; (3) = "dog"; (4) <> "rat" or "mouse" or "dog".
Sort rule for multiple "Effect levels": Field "Effect type" = (1) "carcinogenicity"; (2) <> "carcinogenicity".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on carcinogenicity (other routes) are summarised in the following table:

Table 68. Studies on carcinogenicity (other routes)

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Route of administration> <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>) Neoplastic effects observed in any test group: <Histopathology: neoplastic>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Carcinogenicity (other routes)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Carcinogenicity (other routes) (<Route of administration>) *[Rule: Print if field "Route of administration" is populated.]*

Information requirement: Carcinogenicity (Route: not specified) *[Rule: Print if field "Route of administration" is empty.]*

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.8.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 69. Exposure-related observations on carcinogenicity in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "carcinogenicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is*	<Author> <Year>

		populated]	

5.8.3. Summary and discussion of carcinogenicity

[IUCLID source: Endpoint summary 7.7 Carcinogenicity.]

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA (route: oral):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Value used for CSA (route: dermal):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Value used for CSA (route: inhalation):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))
Target organs: <Target organ>

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

[IUCLID source: section 7.8.1 Toxicity to reproduction.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "rabbit"; (3) "guinea pig"; (4) "mouse"; (5) any other or empty.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on fertility are summarised in the following table:

Table 70. Studies on fertility

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Toxicity for reproduction / fertility (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Toxicity for reproduction (<Test type>) (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Toxicity to reproduction: other studies

[IUCLID source: section 7.8.3 Toxicity to reproduction: other studies.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "rabbit"; (3) "guinea pig"; (4) "mouse"; (5) any other or empty.]

The results of studies on the toxicity to reproduction (other studies) are summarised in the following table:

Table 71. Studies on the toxicity to reproduction (other studies)

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Toxicity to reproduction (other studies) (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Toxicity to reproduction: other studies (<Route of administration>) (<Type of method>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.9.1.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 72. Exposure-related observations on toxicity to reproduction / fertility in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "toxicity to reproduction / fertility". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "toxicity to reproduction / fertility". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "toxicity to reproduction / fertility". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "toxicity to reproduction / fertility". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

[IUCLID source: section 7.8.2 Developmental toxicity / teratogenicity.
Sort rule in tables: (I.) Field "Purpose flag" = (1) "key study"; (2) "supporting study"; (3) "weight of evidence"; (4) "disregarded study"; (II.) Field "Species" = (1) "rat"; (2) = "rabbit"; (3) "guinea pig"; (4) "mouse"; (5) any other or empty.]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on developmental toxicity are summarised in the following table:

Table 73. Studies on developmental toxicity

Method	Results	Remarks	Reference

<Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Effect type>): <Effect level> based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Developmental toxicity / teratogenicity (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Developmental toxicity / teratogenicity (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.9.2.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 74. Exposure-related observations on the developmental toxicity in humans

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "developmental toxicity / teratogenicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "developmental toxicity / teratogenicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			

Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "developmental toxicity / teratogenicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "developmental toxicity / teratogenicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.9.3. Summary and discussion of reproductive toxicity

[IUCLID source: Endpoint summary 7.8 Toxicity to reproduction.]

Effects on fertility

<Effects on fertility, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Effects on fertility, Short description of key information>

Value used for CSA (route: oral):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: dermal):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: inhalation):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

Developmental toxicity

<Developmental toxicity / teratogenitic, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Developmental toxicity / teratogenitic, Short description of key information>

Value used for CSA (route: oral):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: dermal):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: inhalation):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

Toxicity to reproduction: other studies

<Toxicity to reproduction: other studies, Discussion>

The following information is taken into account for any hazard / risk assessment:

<Toxicity to reproduction: other studies, Short description of key information>

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

[IUCLID source: section 7.9.1 Neurotoxicity.
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on neurotoxicity are summarised in the following table:

Table 75. Studies on neurotoxicity

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Generation (if applicable)>): <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Neurotoxicity (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Neurotoxicity (<Test type>) (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.10.1.2. Immunotoxicity

[IUCLID source: section 7.9.2 Immunotoxicity.
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of studies on immunotoxicity are summarised in the following table:

Table 76. Studies on immunotoxicity

Method	Results	Remarks	Reference
<Species> (<Strain>) <Sex> <Test type> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline>	<Endpoint>: <Effect level> (<Sex>) based on: (<Effect concentration type>) (<Basis for effect level / Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

<Principles of method if other than guideline>			

Data waiving

Information requirement: Immunotoxicity (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Immunotoxicity (<Test type>) (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.10.1.3. Specific investigations: other studies

[IUCLID source: section 7.9.3 Specific investigations: other studies.
Sort rule in tables: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results of specific investigations (other studies) are summarised in the following table:

Table 77. Specific investigations: other studies

Method	Results	Remarks	Reference
Endpoint addressed: <Endpoint addressed> Type of effects studied: <Type of effects studied> (<Type of method>) <Species> (<Strain>) <Sex> <Route of administration> (<Type of inhalation exposure (if applicable)>) <Doses / concentrations> (<Basis>) Vehicle: <Vehicle> Exposure: <Duration of treatment / exposure> (<Frequency of treatment>) <Guideline> <Principles of method if other than guideline>	<Details on results>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Specific investigations: other studies (Type of effects studied: <Type of effects studied>) (<Type of method>) (<Route of administration>)

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Specific investigations: other studies (Type of effects studied: <Type of effects studied>) (<Type of method>) (<Route of administration>)

Proposed test guideline: <Guideline>

Species: <Species> (<Strain>) <Sex>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

5.10.2. Human information

No relevant information available *[Rule: Print if applicable, i.e. if field "Endpoint addressed" does not contain the relevant endpoint in any available record.]*

The exposure-related observations in humans are summarised in the following table:

Table 78. Exposure-related observations on neurotoxicity

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "neurotoxicity". Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]			

Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "neurotoxicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Table 79. Exposure-related observations on immunotoxicity

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "immunotoxicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "immunotoxicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "immunotoxicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			

Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "immunotoxicity". *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Table 80. Exposure-related observations: endpoint not specified

Method	Results	Remarks	Reference
[IUCLID source: section 7.10.1 Health surveillance data, if "Endpoint addressed" = "not applicable" or empty. *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.2 Epidemiological data, if "Endpoint addressed" = "not applicable" or empty. *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Study type> <Type of population> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.3 Direct observations: clinical cases, poisoning incidents and other, if "Endpoint addressed" = "not applicable" or empty. *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4)*			

"disregarded study".]			
Study type: <Study type> <Type of population> Subjects: <Subjects> Endpoint addressed: <Endpoint addressed>	<Results of examinations> Outcome of incidence: <Outcome of incidence>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 7.10.5 Exposure related observations in humans, if "Endpoint addressed" = "not applicable" or empty. *Sort rule: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]*			
Study type: <Type of information> Details on study design: <Details on study design> Endpoint addressed: <Endpoint addressed>	<Results>	<Reliability> <Purpose flag> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

5.10.3. Summary and discussion of other effects

Neurotoxicity *[IUCLID source: Endpoint summary 7.9.1 Neurotoxicity.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA (route: oral):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: dermal):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: inhalation):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.)
[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]

Immunotoxicity *[IUCLID source: Endpoint summary 7.9.2 Immunotoxicity.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Value used for CSA (route: oral):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: dermal):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Value used for CSA (route: inhalation):

<Endpoint conclusion> (<Effect level>: <Effect level value> <Effect level Unit> (<Test type>; <Species>))

Justification for classification or non classification *[Rule: This subheading is not printed if the corresponding source field is empty and all fields "Endpoint conclusion" contain either "No study available" or "No study available (further information necessary)".]*

<Justification for classification or non-classification>

Discussion of human information:

See "Summary and discussion of human information" in chapter 5 HUMAN HEALTH HAZARD ASSESSMENT. (Note: As appropriate, copy any relevant information from there or delete this default text.) *[Rule: This subheading and default text are only inserted if at least one endpoint study record is available in the overview table of human information for this endpoint (indirect evidence that these studies are discussed in the Endpoint summary 7.10).]*

Specific investigations: other studies *[IUCLID source: Endpoint summary 7.9.3 Specific investigations: other studies.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

Table 81. Available dose-descriptor(s) per endpoint as a result of its hazard assessment.

[IUCLID source: endpoint summaries of relevant subsections of section 7 "Toxicological information"
Rule 1: Print a row for a given Endpoint/Route only if any data are available for the 3rd column.
Rule 2: <Endpoint conclusion> is always printed in 3rd column if this field is populated.
Rule 3: Print in 3rd column: >>>CAUTION: "No study available" in corresponding IUCLID endpoint summary, although an Effect level is provided.<<<" if applicable (except for "Sensitisation" and "Mutagenicity").
Rule 4: Print in 3rd column: ">>>CAUTION: "Adverse effect observed" in corresponding IUCLID endpoint summary, but no Effect level is provided.<<<" if applicable (except for "Sensitisation" and "Mutagenicity").
Rule 5: In 4th column, print "(<Author> <Year>) (see section xxx) as triggered by the source field "Endpoint selection". Instead of the record name which is indicated in this field, the values for Author and Year are extracted from the referenced endpoint study record if a link is provided. In addition a reference to the relevant CSR section is printed, but only if a bibliographic reference is provided.]

[Please note: If the link entered in any field "Endpoint selection" was deleted in the IUCLID source dataset, no reference (Author + Year) can be output. This can happen either by intentionally removing the link or removing the related endpoint study record.]

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
Acute toxicity	oral	<Endpoint conclusion> e.g. No adverse effect observed *[see rules above]* <Effect level>: <Value> <Unit> e.g. LD50: 20 mg/kg bw	(<Author> <Year>) (see section 5.2.1.1) e.g. Smith T.E. et al. 1999 (see section 5.2.1.1)
Acute toxicity	dermal	<Endpoint conclusion> <Effect level>: <Value> <Unit>	(<Author> <Year>) (see section 5.2.1.3)
Acute toxicity	inhalation	<Endpoint conclusion> <Effect level>: <Value> <Unit>	(<Author> <Year>) (see section 5.2.1.2)
Irritation / Corrosivity	skin	<Endpoint conclusion> <Effect level> e.g. highly irritating	(<Author> <Year>) (see section 5.3.1.1)
Irritation / Corrosivity	eye	<Endpoint conclusion> <Effect level>	(<Author> <Year>) (see section 5.3.2.1)
Irritation / Corrosivity	resp. tract	<Endpoint conclusion> <Effect level>	
Sensitisation	skin	<Endpoint conclusion>	(<Author> <Year>) (see section 5.5.1.1)
Sensitisation	resp. tract	<Endpoint conclusion>	(<Author> <Year>) (see section 5.5.2.1)
Repeated dose toxicity	oral	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>	(<Author> <Year>) (see section 5.6.1.1)

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
		e.g. NOAEL: 12 mg/kg bw/day (chronic; rat)Target organs: cardiovascular / hematological: spleen	
Repeated dose toxicity	dermal (systemic effects)	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>	(<Author> <Year>) (see section 5.6.1.3)
Repeated dose toxicity	dermal (local effects)	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.6.1.3)
Repeated dose toxicity	inhalation (systemic effects)	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>	(<Author> <Year>) (see section 5.6.1.2)
Repeated dose toxicity	inhalation (local effects)	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.6.1.2)
Mutagenicity	in vitro / in vivo	<Endpoint conclusion>	(<Author> <Year>) (see section 5.7.1 / 5.7.2) see section 5.7.1 / 5.7.2 *[Rule: Print if field "Endpoint selection" is empty, but either "No adverse effect observed (negative)" or "Adverse effect observed (positive)" was entered in "Endpoint conclusion". Note: This is to cover cases where no single endpoint study is identified because the conclusion is based on several studies.]*
Carcinogenicity	oral	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>	(<Author> <Year>) (see section 5.8.1.1)
Carcinogenicity	dermal	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>	(<Author> <Year>) (see section 5.8.1.3)
Carcinogenicity	inhalation	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>) Target organs: <Target organ>	(<Author> <Year>) (see section 5.8.1.2)
Reproductive toxicity: effects on fertility	oral	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.9.1.1)
Reproductive toxicity: effects on fertility	dermal	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.9.1.1)

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
Reproductive toxicity: effects on fertility	inhalation	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.9.1.1)
Reproductive toxicity: developmental toxicity	oral	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.9.2.1)
Reproductive toxicity: developmental toxicity	dermal	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.9.2.1)
Reproductive toxicity: developmental toxicity	inhalation	<Endpoint conclusion> <Effect level>: <Value> <Unit> (<Test type>; <Species>)	(<Author> <Year>) (see section 5.9.2.1)

Justification for endpoint selection:

- Acute toxicity (oral): <Justification for selection> *[Rule: Print bulleted paragraph if source field is populated.]*
- *cont'd for each endpoint*

5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects

Table 82. Hazard conclusions for workers
[IUCLID source: Endpoint summary 7. Toxicological information.]

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> *[Rule 1: If DNEL or DMEL or "other toxicological threshold" selected.]* *e.g.* *DNEL: 24.7 mg/m³* <Hazard assessment conclusion> *[Rule 2: If phrase, but no DNEL or DMEL or "other toxicological threshold" selected.]* *e.g.* *Low hazard (no threshold derived)* >>>CAUTION: IUCLID field "Hazard assessment conclusion" populated with an obsolete value migrated from a previous version.<<< *[Rule 3: Print if any of the values is selected that appear greyed in the corresponding IUCLID picklist, e.g. "No data available: testing technically not feasible (obsolete)".]*	<Most sensitive endpoint> <(Route of original study)> *e.g.* *Repeated dose toxicity (Oral)*
	Systemic effects - Acute	<Hazard assessment conclusion>: <DNEL value> <Unit> *[Rule 1: If DNEL or "other toxicological threshold" selected.]* <Hazard assessment conclusion> *[Rule 2: If phrase, but no DNEL or "other toxicological threshold" selected.]*	<Most sensitive endpoint> <(Route of original study)>
	Local effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> *[Rule 1 as for Systemic effects - Long-term]* <Hazard assessment conclusion> *[Rule 2 as for Systemic effects - Long-term]*	<Most sensitive endpoint>
	Local effects - Acute	<Hazard assessment conclusion>: <DNEL value> <Unit> *[Rule 1as for Systemic effects - Acute]* <Hazard assessment conclusion> *[Rule 2 as for Systemic effects - Acute]*	<Most sensitive endpoint>
Dermal	Systemic effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> *[Rule 1 as for Inhalation Systemic effects - Long-term]* *e.g.* *DNEL: 7 mg/kg bw/day* <Hazard assessment conclusion> *[Rule 2 as for Inhalation Systemic effects - Long-term]* *e.g.* *No hazard identified*	<Most sensitive endpoint><(Route of original study)> *e.g.* *Repeated dose toxicity (oral)*
	Systemic effects -	<Hazard assessment conclusion>: <DNEL value> <Unit> *[Rule 1 as for*	<Most sensitive endpoint><(Route of original study)>

	Acute	*Inhalation Systemic effects - Acute]* <Hazard assessment conclusion> *[Rule 2 as for Inhalation Systemic effects - Acute]*	
	Local effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> *[Rule 1 as for Inhalation Systemic effects - Long-term]* <Hazard assessment conclusion> *[Rule 2 as for Inhalation Systemic effects - Long-term]*	<Most sensitive endpoint>
	Local effects - Acute	<Hazard assessment conclusion>: <DNEL value> <Unit> *[Rule 1 as for Inhalation Systemic effects - Acute]* <Hazard assessment conclusion> *[Rule 2 as for Inhalation Systemic effects - Acute]*	<Most sensitive endpoint>
Eyes	Local effects	<Hazard assessment conclusion> *e.g.* *No hazard identified*	

Further explanation on hazard conclusions: *[Rule: Print only if at least one source field "Justification and comments" is populated.]*

- **Inhalation Systemic effects - Long-term:** <Justification and comments> *[Rule: Print bulleted paragraph if source field is populated for this route / type of effects.]*

- *cont'd for each route / type of effects*

Table 83. Further explanation on DNEL derivation for workers

[IUCLID source: Endpoint summary 7. Toxicological information.
Rule 1: Print table only if at least one of the source fields specified in the table below is populated.
Rule 2: Create a row for a given Route / Type of effect if at least one of the source fields related to that item is populated.
Rule 3: Items (e.g. AF for dose response relationship: <AF for dose response relationship> (<Justification>)) are only printed if information is retrieved from the corresponding source field(s).
Rule 4: AF items are skipped if AF = 1 and the related field "Justification" is empty.]

Route / Type of effect	DNEL derivation	Assessment factors (AF) for DNEL derivation
Inhalation Systemic effects - Long-term	**DNEL derivation method:** <DNEL derivation method> *e.g.* ***DNEL derivation method:*** *ECHA REACH guidance* **Dose descriptor starting point:** <Dose descriptor starting point> *e.g.* ***Dose descriptor starting point:*** *NOAEC = 617 mg/m³*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) *e.g.* ***AF for difference in duration of exposure:*** *2 (DNEL is based on an oral 90 day study)* **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> *e.g.* ***AF for interspecies differences (allometric scaling):*** *1 (AF not used for inhalation route)* **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Inhalation Systemic effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point> *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is not ticked.]* **Dose descriptor starting point:** <Dose descriptor starting point> (long-term; extrapolated to acute/short-term) *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is ticked.]*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Inhalation Local effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure>

		(<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Inhalation Local effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point> *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is not ticked.]* **Dose descriptor starting point:** <Dose descriptor starting point> (long-term; extrapolated to acute/short-term) *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is ticked.]*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Systemic effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Systemic effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point> *[Rule: Print if*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences

	source field populated and tickbox "DNEL extrapolated from long term DNEL" is not ticked.] **Dose descriptor starting point:** <Dose descriptor starting point> (long-term; extrapolated to acute/short-term) *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is ticked.]*	(allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Local effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Local effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**

Justification for route-to-route extrapolation: *[Rule: Print only if at least one source field "Justification for route-to-route extrapolation" is populated.]*

- **Inhalation Systemic effects - Long-term:** <Justification for route-to-route extrapolation> *[Rule: Print bulleted paragraph if source field is populated for this route / type of effects.]*

e.g.

- ***Inhalation Systemic effects - Long-term:*** *NOAECcorr=NOAELoral *(1/0.38 m³/kg/d)*(ABSoral-*

rat/ABSinh-human)(6.7 m³ (8h)/10 m³ (8h)) = 700 mg/kg/d*(1/0.38 m³/kg/d)*(0.5*1)*0.67=617 mg/m³.*
It is assumed that oral absorption rate is 50% of that of inhalation absorption.
ABSoral/rat=oral absorption rate in rats, ABSinh./human=inhalation absorption rate in humans

- *cont'd for each route / type of effects*

Discussion *[Rule: Print if the source field is populated.]*

<Results and discussions, Workers, Discussion>

Table 84. Hazard conclusions for the general population
[Rules: as stated for workers]

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint> <(Route of original study)>
	Systemic effects - Acute	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint> <(Route of original study)>
	Local effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint>
	Local effects - Acute	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint>
Dermal	Systemic effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint> <(Route of original study)>
	Systemic effects - Acute	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint> <(Route of original study)>
	Local effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint>
	Local effects - Acute	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint>
Oral	Systemic effects - Long-term	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint> <(Route of original study)>
	Systemic effects - Acute	<Hazard assessment conclusion>: <DN(M)EL value> <Unit> <Hazard assessment conclusion>	<Most sensitive endpoint> <(Route of original study)>
Eyes	Local effects	<Hazard assessment conclusion>	

Further explanation on hazard conclusions: *[Rules: as stated for workers]*

- **Inhalation Systemic effects - Long-term:** <Justification and comments>

- *cont'd for each route / type of effects*

Table 85. Further explanation on DNEL derivation for the general population
[IUCLID source: Endpoint summary 7. Toxicological information. Rules: as stated for workers]

Route / Type of effect	DNEL derivation	Assessment factors (AF) for DNEL derivation
Inhalation Systemic effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Inhalation Systemic effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point> *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is not ticked.]* **Dose descriptor starting point:** <Dose descriptor starting point> (long-term; extrapolated to acute/short-term) *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is ticked.]*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Inhalation Local effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties>

		Overall Assessment Factor: <Overall Assessment Factor>
Inhalation Local effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Systemic effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Systemic effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point> *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is not ticked.]* **Dose descriptor starting point:** <Dose descriptor starting point> (long-term; extrapolated to acute/short-term) *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is ticked.]*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**

Dermal Local effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Dermal Local effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**
Oral Systemic effects - Long-term	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point>	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for difference in duration of exposure:** <AF for difference in duration of exposure> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**

Oral Systemic effects - Acute	**DNEL derivation method:** <DNEL derivation method> **Dose descriptor starting point:** <Dose descriptor starting point> *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is not ticked.]* **Dose descriptor starting point:** <Dose descriptor starting point> (long-term; extrapolated to acute/short-term) *[Rule: Print if source field populated and tickbox "DNEL extrapolated from long term DNEL" is ticked.]*	**AF for dose response relationship:** <AF for dose response relationship> (<Justification>) **AF for interspecies differences (allometric scaling):** >AF for interspecies differences (allometric scaling)> **AF for other interspecies differences:** <AF for other interspecies differences> **AF for intraspecies differences:** <AF for intra species differences> **AF for the quality of the whole database:** <AF for the quality of the whole database> **AF for remaining uncertainties:** <AF for remaining uncertainties> **Overall Assessment Factor: <Overall Assessment Factor>**

Justification for route-to-route extrapolation: *[Rule: Print only if at least one source field "Justification for route-to-route extrapolation" is populated.]*

- **Inhalation Systemic effects - Long-term:** <Justification for route-to-route extrapolation> *[Rule: Print bulleted paragraph if source field is populated for this route / type of effects.]*
- *cont'd for each route / type of effects*

Discussion *[Rule: Print if the source field is populated.]*

<General population, Discussion>

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

[IUCLID source: section 4.14 Explosiveness.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The available information on explosivity is summarised in the following table:

Table 86. Information on explosivity

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> Study results: Explosive under influence of flame: <Explosive under influence of flame> More sensitive to shock than m-dinitrobenzene: <More sensitive to shock than m-dinitrobenzene> More sensitive to friction than m-dinitrobenzene: <More sensitive to friction than m-dinitrobenzene> Explosive (not specified): <Explosive (not specified)> Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving: see CSR section 1.3 Physicochemical properties. *[Insert if field "Data waiving" is populated in any record of IUCLID section 4.14.]*

Testing proposal: see CSR section 1.3 Physicochemical properties. *[Insert if field "Study result type" contains "experimental study planned" in any record of IUCLID section 4.14.]*

Discussion *[IUCLID source: Endpoint summary 4.14 Explosiveness.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Classification according to GHS: *[IUCLID source: section 2.1 GHS.]*

Name: <Name>

Related composition: <Related composition>

State / form of the substance: <Form of the substance>

Classification: <Explosives> (Hazard statement: <Hazard statement>)

Reason for no classification: <Reason for no classification>

Classification according to DSD / DPD

Classification status: <Status> <(Name)> *[IUCLID source: section 2.2 DSD - DPD. Condition: <Status> <(Reference substance name)> is inserted if <Name> not available.]*

<Explosiveness>

Reason for no classification: <Reason for no classification>

Justification for classification or non-classification: <Justification for classification or non-classification>

6.2. Flammability

[IUCLID source: section 4.13 Flammability / 4.11 Flash point.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

Flammability *[Rule: Print subheading if information is available for both "Flammability" and "Flash point"]*

The available information on flammability is summarised in the following table:

Table 87. Information on flammability

Method	Results	Remarks	Reference
<Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> Study results: Ignition on contact with air: <Solid/liquid: Ignition on contact with air> (<Remarks>) Release of flammable gas in contact with water: <Solid/liquid: Release of flammable gas in contact with water> (<Remarks>) Burning time (s): <Solid: Burning time (s)> (<Remarks>) Flame extension (cm): <Aerosol: Flame extension (cm)> (<Remarks>) Flame projection (cm): <Aerosol: Flame projection (cm)> (<Remarks>) Lower explosion limit (%): <Gas: Lower explosion limit (%)> (<Remarks>) Upper explosion limit (%): <Gas: Upper explosion limit (%)> (<Remarks>) Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving: see CSR section 1.3 Physicochemical properties. *[Insert if field "Data waiving" is populated in any record of IUCLID section 4.13.]*

Testing proposal: see CSR section 1.3 Physicochemical properties. *[Insert if field "Study result type" contains "experimental study planned" in any record of IUCLID section 4.13.]*

Discussion *[IUCLID source: Endpoint summary 4.13 Flammability.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Flash point *[Rule: Print subheading if information is available for both "Flammability" and "Flash point"]*

No relevant information available *[Rule: Print if applicable]*

The available information on flash point is summarised in the following table:

Table 88. Information on flash point

Method	Results	Remarks	Reference
Determination of flash point <Type of method> <Guideline> <Principles of method if other than guideline>	Flash point: <Flash point> at <Pressure> (<Remarks>) Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving: see CSR section 1.3 Physicochemical properties. *[Insert if field "Data waiving" is populated in any record of IUCLID section 4.11.]*

Testing proposal: see CSR section 1.3 Physicochemical properties. *[Insert if field "Study result type" contains "experimental study planned" in any record of IUCLID section 4.11.]*

Discussion *[IUCLID source: Endpoint summary 4.11 Flash point.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Classification according to GHS: *[IUCLID source: section 2.1 GHS.]*

Name: <Name>

Related composition: <Related composition>

State / form of the substance: <Form of the substance>

Classification: <Explosives> (Hazard statement: <Hazard statement>)

Reason for no classification: <Reason for no classification>

Classification according to DSD / DPD

Classification status: <Status> <(Name)> *[IUCLID source: section 2.2 DSD - DPD. Condition: <Status> <(Reference substance name)> is inserted if <Name> not available.]*

<Flammability>

Reason for no classification: <Reason for no classification> *[Inserted if field "Reason for no classification" is populated AND "Status" <> "67/548/EEC annex 1".]*

Justification for classification or non-classification: <Justification for classification or non-classification>

6.3. Oxidising potential

[IUCLID source: section 4.15 Oxidising properties.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The available information on the oxidising potential is summarised in the following table:

Table 89. Information on oxidising potential

Method	Results	Remarks	Reference
Contact with: <Contact with> (<Duration of test (contact time)>) <Guideline> <Principles of method if other than guideline>	Evaluation of results: <Interpretation of results> <Test result, result>: <Test result, range> (<Remarks>) Remarks: <Any other information on results incl. tables>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving: see CSR section 1.3 Physicochemical properties. *[Insert if field "Data waiving" is populated in any record of IUCLID section 4.15.]*

Testing proposal: see CSR section 1.3 Physicochemical properties. *[Insert if field "Study result type" contains "experimental study planned" in any record of IUCLID section 4.15.]*

Discussion *[IUCLID source: Endpoint summary 4.15 Oxidising properties.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

Classification according to GHS: *[IUCLID source: section 2.1 GHS.]*

Name: <Name>

Related composition: <Related composition>

State / form of the substance: <Form of the substance>

Classification: <Explosives> (Hazard statement: <Hazard statement>)

Reason for no classification: <Reason for no classification>

Classification according to DSD / DPD

Classification status: <Status> <(Name)> *[IUCLID source: section 2.2 DSD - DPD. Condition: <Status> <(Reference substance name)> is inserted if <Name> not available.]*

<Oxidising properties>

Reason for no classification: <Reason for no classification> *[Inserted if field "Reason for no classification" is populated AND "Status" <> "67/548/EEC annex 1".]*

Justification for classification or non-classification: <Justification for classification or non-classification>

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

<Discussion> *[IUCLID source: Endpoint summary 6.1 Aquatic toxicity.]*

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

[IUCLID source: section 6.1.1 Short-term toxicity to fish.
Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture according to the following order of priority: "LC50-96 h / 4 d", "LC50-72 h / 3 d", "LC50-48 h" / 2 d", "LC50-24 h / 1 d", "LC50", or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": (I.) Field "Endpoint" = (1) "LC50"; (2) "LC0"; (3) "LC100"; (4) any other; (II.) Field "Duration+Unit" (1) "96 h"; (2) "4 d"; (3) "72 h"; (4) "3 d"; (5) "48 h"; (6) "2 d"; (7) "24 h"; (8) "1 d"; (9) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 90. Short-term effects on fish

Method	Results	Remarks	Reference
<*Test organisms (species)*> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Short-term toxicity testing on fish

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Short-term toxicity testing on fish

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.1.1 Short-term toxicity to fish.]*

<Discussion>

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

LC50 for freshwater fish: <LC50 for freshwater fish> <Unit>

LC50 for marine water fish: <LC50 for marine water fish> <Unit>

7.1.1.2. Long-term toxicity to fish

[IUCLID source: section 6.1.2 Long-term toxicity to fish.
Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture according to the following order of priority: "NOEC", "LOEC", "EC10", "IC10" or "LC10" or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10"; (4) "LC10"; (5) "IC10"; (6) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 91. Long-term effects on fish

Method	Results	Remarks	Reference
<*Test organisms (species)*> <Water media type> <Life stage / endpoint studied> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Long-term toxicity testing on fish

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Long-term toxicity testing on fish (<Life stage/ endpoint studied>) *[Depending on the phrase selected in this IUCLID field, one of the following test types is specified: "early-life stage: reproduction, (sub)lethal effects" (or "life cycle: reproduction, (sub)lethal effects"), "embryo and sac-fry stage: (sub)lethal effects", "juvenile fish: growth".]*

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.1.2 Long-term toxicity to fish.]*

<Discussion>

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC10/LC10 or NOEC for freshwater fish: <EC10/LC10 or NOEC for freshwater fish> <Unit>

EC10/LC10 or NOEC for marine water fish: <EC10/LC10 or NOEC for marine water fish> <Unit>

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

[IUCLID source: section 6.1.3 Short-term toxicity to aquatic invertebrates.
Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture according to the following order of priority: "EC/IC/LC50-24 h / 1 d", "EC/IC/LC50-48 h / 2 d", "EC/IC/LC50", any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": (I.) Field "Endpoint" = (1) "EC50" or "IC50" or "LC50"; (2) "EC0" or "IC0" or "LC0"; (3) "EC100" or "LC100"; (4) any other; (II.) Field "Duration+Unit" = (1) "48 h"; (2) "2 d"; (3) "24 h"; (4) "1 d"; (5) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 92. Short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Short-term toxicity testing on aquatic invertebrates

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Short-term toxicity testing on aquatic invertebrates

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.1.3 Short-term toxicity to aquatic invertebrates.]*

<Discussion>

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC50/LC50 for freshwater invertebrates: <EC50/LC50 for freshwater invertebrates> <Unit>

EC50/LC50 for marine invertebrates: <EC50/LC50 for marine invertebrates> <Unit>

7.1.2.2. Long-term toxicity to aquatic invertebrates

[IUCLID source: section 6.1.4 Long-term toxicity to aquatic invertebrates.
Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10" or "LC10" or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10"; (4) "LC10"; (5) "IC10"; (6) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 93. Long-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
<*Test organisms (species)*> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Long-term toxicity testing on aquatic invertebrates

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Long-term toxicity testing on aquatic invertebrates

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.1.4 Long-term toxicity to aquatic invertebrates.]*

<Discussion>

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC10/LC10 or NOEC for freshwater invertebrates: <EC10/LC10 or NOEC for freshwater invertebrates> <Unit>

EC10/LC10 or NOEC for marine invertebrates: <EC10/LC10 or NOEC for marine invertebrates> <Unit>

7.1.3. Algae and aquatic plants

[IUCLID source: sections 6.1.5 Toxicity to aquatic algae and cyanobacteria / 6.1.6 Toxicity to aquatic plants other than algae.
Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "EC20", "IC20", "EC50", or "IC50", or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": (I.) Field "Endpoint" = (1) "EC50" or "IC50"; (2) "NOEC"; (3) "LOEC"; (4) "EC10" or "IC10", (5) "EC20" or "IC20; (6) "EC0" or "IC0"; (7) "EC100" or "IC100"; (8) any other; (II.) Field "Duration+Unit" (1) "96 h"; (2) "4 d"; (3) "72 h"; (4) "3 d"; (5) "48 h"; (6) "2 d"; (7) "24 h"; (8) "1 d"; (9) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 94. Effects on algae and aquatic plants

Method	Results	Remarks	Reference
[IUCLID source: section 6.1.5 Toxicity to aquatic algae and cyanobacteria.]			
<*Test organisms (species)*> (algae) <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

[IUCLID source: section 6.1.6 Toxicity to aquatic plants other than algae.]			
<Test organisms (species)> (aquatic plants) <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Growth inhibition study with algae / cyanobacteria / Growth inhibition study with aquatic plants other than algae *[If record in section 6.1.5 / 6.1.6, respectively.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Effects on algae *[If record in section 6.1.5]*

Information requirement: Effects on aquatic plants *[If record in section 6.1.6]*

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion

Effects on algae / cyanobacteria *[IUCLID source: Endpoint summary 6.1.5 Toxicity to aquatic algae and cyanobacteria.]*

<Discussion>

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC50/LC50 for freshwater algae: <EC50/LC50 for freshwater algae> <Unit>

EC50/LC50 for marine water algae: <EC50/LC50 for marine water algae> <Unit>

EC10/LC10 or NOEC for freshwater algae: <EC10/LC10 or NOEC for freshwater algae> <Unit>

EC10/LC10 or NOEC for marine water algae: <EC10/LC10 or NOEC for marine water algae> <Unit>

Effects on aquatic plants other than algae *[IUCLID source: Endpoint summary 6.1.6 Toxicity to aquatic plants other than algae.]*

<Discussion>

The following information is taken into account for effects on aquatic plants other than algae for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC50/LC50 for freshwater plants: <EC50/LC50 for freshwater plants> <Unit>

EC50/LC50 for marine water plants: <EC50/LC50 for marine water plants> <Unit>

EC10/LC10 or NOEC for freshwater plants: <EC10/LC10 or NOEC for freshwater plants> <Unit>

EC10/LC10 or NOEC for marine water plants: <EC10/LC10 or NOEC for marine water plants> <Unit>

7.1.4. Sediment organisms

[IUCLID source: section 6.2 Sediment toxicity.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "LC10", "LD10" "EC50","LC50", "LD50" or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) "EC0" or "LC0" or "LD0"; (6) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 95. Effects on sediment organisms

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test duration type> (<Study type>) <Test type> Sediment: <Type of sediment> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Effects on sediment organisms

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Effects on sediment organisms

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type> (<Study type>) (<Test duration type>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.2 Sediment toxicity.]*

<Discussion>

The following information is taken into account for sediment toxicity for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC50/LC50 for freshwater sediment: <EC50/LC50 for freshwater sediment> <Unit>

EC50/LC50 for marine water sediment: <EC50/LC50 for marine water sediment> <Unit>

EC10/LC10 or NOEC for freshwater sediment: <EC10/LC10 or NOEC for freshwater sediment> <Unit>

EC10/LC10 or NOEC for marine water sediment: <EC10/LC10 or NOEC for marine water sediment> <Unit>

7.1.5. Other aquatic organisms

[IUCLID source: section 6.1.8 Toxicity to other aquatic organisms.
Sort rule in table: (I.) Field "Water media type" = (1) "freshwater"; (2) "brackish water"; (3) "saltwater"; (4) "no data" or empty; (II.) Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "LC10" "EC50","IC50", "LC50" or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "IC10" or "LC10"; (4) "EC50" or "IC50" or "LC50"; (5) "EC0" or "IC0" or "LC0"; (6) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 96. Effects on other aquatic organisms

Method	Results	Remarks	Reference
<Test organisms (species)> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Effects on other aquatic organisms

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Effects on other aquatic organisms

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.1.8 Toxicity to other aquatic organisms.]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

7.2. Terrestrial compartment

<Discussion> *[IUCLID source: Endpoint summary 6.3 Terrestrial toxicity.]*

7.2.1. Toxicity to soil macro-organisms

[IUCLID source: sections 6.3.1 Toxicity to soil macroorganisms except arthropods / 6.3.2 Toxicity to terrestrial arthropods (For records in section 6.3.2 only, if soil macro-organisms are involved as triggered by the absence of any indication of non-soil organisms in the following fields:"Guideline", "Application method", "Test organisms", "Animal group" or if all four trigger fields are blank..
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "LC10", "LD10" "EC50","LC50", "LD50" or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 97. Effects on soil macro-organisms

Method	Results	Remarks	Reference
[IUCLID source: section 6.3.1 Toxicity to soil macroorganisms except arthropods.]			
<*Test organisms (species)*> (<Animal group>) <Test duration type> (<Study type>) Substrate: <Substrate type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>
[IUCLID source: section 6.3.2 Toxicity to terrestrial arthropods.]			
<*Test organisms (species)*> (<Animal group>) Application method: <Application method> *[Rule: If "other:" is selected. Note that the phrase "soil" is ignored as this would be redundant to the table title]* <Test duration type> (<Study type>)	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]*	<Author> <Year>

<Guideline> <Principles of method if other than guideline>		Form: <Test material form> [*If field is populated]*	

Data waiving *[Note: Data waivers explicitly indicated for non soil-dwelling organisms are covered by CSR section 7.2.4 Toxicity to other terrestrial organisms).]*

Information requirement: Toxicity to soil macro-organisms except arthropods / Toxicity to soil arthropods *[If record in section 6.3.1 / 6.3.2]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal *[Note: Testing proposals explicitly indicated for non soil-dwelling organisms are covered by CSR section 7.2.4 Toxicity to other terrestrial organisms).]*

Information requirement: Short-term toxicity testing on invertebrates / Long-term toxicity testing on invertebrates / Toxicity testing on invertebrates *[If record in section 6.3.1 or 6.3.2 with "Test duration type" = "short-term toxicity" / 6.3.1 or 6.3.2 with "Test duration type" = "long-term toxicity" / 6.3.1 or 6.3.2 with "Test duration type" = empty, respectively.]*

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Animal group>)

Study type: <Study type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion of effects on soil macro-organisms except arthropods *[IUCLID source: Endpoint summary 6.3.1 Toxicity to soil macroorganisms except arthropods.]*

<Discussion>

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

Short-term EC50 or LC50 for soil macro-organisms: <Short-term EC50 or LC50 for soil macro-organisms> <Unit>

Long-term EC10/LC10 or NOEC for soil macro-organisms: <Long-term EC10/LC10 or NOEC for soil macro-organisms> <Unit>

Discussion of effects on soil dwelling arthropods *[IUCLID source: Endpoint summary 6.3.2 Toxicity to terrestrial arthropods.]*

>>>NOTE (please delete this instruction): Move any information related to other than soil arthropods to the CSR section" 7.2.4 Toxicity to other terrestrial organisms"<<< *[Insert if the fields "Guideline", "Application method", "Animal group" and "Test organisms (species)" do not contain any of the predefined phrases and are not blank (meaning that "other:" is selected). For such cases it cannot be decided if the study is with soil or non-soil organisms.]*

<Discussion>

The following information is taken into account for effects on soil dwelling arthropods for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

Short-term EC50 or LC50 for soil dwelling arthropods: <Short-term EC50 or LC50 for soil dwelling arthropods> <Unit>

Long-term EC10/LC10 or NOEC for soil dwelling arthropods: <Long-term EC10/LC10 or NOEC for soil dwelling arthropods> <Unit>

7.2.2. Toxicity to terrestrial plants

[IUCLID source: section 6.3.3 Toxicity to terrestrial plants.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 98. Effects on terrestrial plants

Method	Results	Remarks	Reference
<*Test organisms (species)*> (<Plant group>) <Test duration type> (<Study type>) <Test type> Substrate: <Substrate type> <Guideline> <Principles of method if other than guideline>	<Species> *[Only if effect concentrations for multiple species]*: <Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Effects on terrestrial plants

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Short-term toxicity testing on plants / Long-term toxicity testing on plants / <??? specify: Short/Long-term> toxicity testing on plants *[If "Test duration type" = "short-term toxicity" / "long-term toxicity" / empty, respectively.]*

Proposed test guideline: <Guideline>

<Test organisms (species)> (<Plant group>)

Study type: <Study type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion

<Discussion>

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

Short-term EC50 or LC50 for terrestrial plants: <Short-term EC50 or LC50 for terrestrial plants> <Unit>

Long-term EC10/LC10 or NOEC for terrestrial plants: <Long-term EC10/LC10 or NOEC for terrestrial plants> <Unit>

7.2.3. Toxicity to soil micro-organisms

[IUCLID source: section 6.3.4 Toxicity to soil microorganisms.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "EC10"; (3) "EC25"; (4) "EC50"; (5) "EC100"; (6) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 99. Effects on soil micro-organisms

Method	Results	Remarks	Reference
Species/Inoculum: <Test organisms (inoculum)> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Effects on soil micro-organisms

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Effects on soil micro-organisms

Proposed test guideline: <Guideline>

Species/Inoculum: <Test organisms (inoculum)>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.3.4 Toxicity to soil microorganisms.]*

<Discussion>

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

Short-term EC50 or LC50 for soil micro-organisms: <Short-term EC50 or LC50 for soil micro-organisms> <Unit>

Long-term EC10/LC10 or NOEC for soil micro-organisms: <Long-term EC10/LC10 or NOEC for soil micro-organisms> <Unit>

7.2.4. Toxicity to other terrestrial organisms

[IUCLID source: section 6.3.2 Toxicity to terrestrial arthropods, only, if non-soil organisms are involved as triggered by the absence of any indication of soil macro-organisms but explicit indication of non-soil organisms in the following fields:"Guideline", "Application method", "Test organisms", "Animal group". Note: If no explicit indication of non-soil organisms is given (e.g. all four trigger fields are filled with "other: freetext" or blank), the study is moved to CSR section 7.2.1.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "LC10", "LD10" "EC50","LC50", "LD50" or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "LC10" or "LD10"; (4) "EC50" or "LC50" or "LD50"; (5) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 100. Effects on terrestrial arthropods

Method	Results	Remarks	Reference
<*Test organisms (species)*> (<Animal group>) Application method: <Application method> <Test duration type> (<Study type>) <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving *[Note: Data waivers not explicitly indicated for non-soil organisms are covered by CSR section 7.2.1 Toxicity to soil macro-organisms.]*

Information requirement: Toxicity to terrestrial arthropods other than soil macro-organisms

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal *[Note: Testing proposals not explicitly indicated for non-soil organisms are covered by CSR section 7.2.1 Toxicity to soil macro-organisms.]*

Information requirement: Toxicity to terrestrial arthropods other than soil macro-organisms

Proposed test guideline: <Guideline>

Species: <Test organisms (species)> (<Animal group>)

Test duration type: <Test duration type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.3.2 Toxicity to terrestrial arthropods.]*

>>>NOTE (please delete this instruction): Move any information related to soil arthropods to the CSR section "7.2.1 Toxicity to soil macro-organisms", subheading "Discussion of effects on soil arthropods"<<< *[If field "Discussion" is populated and any field indicates "soil arthropods".]*

<Discussion>

The following information is taken into account for any hazard / risk assessment:

<Short description of key information>

7.3. Atmospheric compartment

>>>NOTE (please delete this instruction): Move any information related to this section manually from other sections (e.g. from "Toxicity to terrestrial plants" (if fumigation study) or from "Toxicity to other terrestrial organisms" (e.g. if spray application study with honeybees).<<< *[Insert if any endpoint study record is captured from section 6.3.3 (Tox. to terr. plants) with field "Study type" = "*field study" or from section 6.3.2 (Tox. to terr. arthropods) with field "Application method" = "spray".]*

7.4. Microbiological activity in sewage treatment systems

[IUCLID source: section 6.1.7 Toxicity to microorganisms.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".
Rule for multiple "Effect concentrations": Capture if "NOEC", "LOEC", "EC10", "IC10", "EC50","IC50", or any other if none of these endpoints applies.
Sort rule for multiple "Effect concentrations": Field "Endpoint" = (1) "NOEC"; (2) "LOEC"; (3) "EC10" or "IC10"; (4) "EC50" or "IC50"; (5) "EC0" or "IC0"; (6) any other.]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 101. Effects on micro-organisms

Method	Results	Remarks	Reference
<*Test organisms (species)*> <Water media type> <Test type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Effects on aquatic micro-organisms

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Effects on aquatic micro-organisms

Proposed test guideline: <Guideline>

Activated sludge / sewage / species: <Test organisms (species)> (<Water media type>)

Test type: <Test type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.1.7 Toxicity to microorganisms.]*

<Discussion>

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

EC50/LC50 for aquatic micro-organisms: <EC50/LC50 for aquatic micro-organisms> <Unit>

EC10/LC10 or NOEC for aquatic micro-organisms: <EC10/LC10 or NOEC for aquatic micro-organisms> <Unit>

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

[IUCLID source: section 6.3.5 Toxicity to birds.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 102. Effects on birds

Method	Results	Remarks	Reference
<Test organisms (species)> <Test type> (<Dose method>) Doses: <Nominal and measured doses / concentrations> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> based on: <Basis for effect> (<Remarks>) Repellency factors: <Repellency factors (if applicable)>	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Long-term or reproductive toxicity to birds / Toxicity to birds *[If "Test type" = "reproduction toxicity" / <> "reproduction toxicity", respectively.]*

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Long-term or reproductive toxicity to birds / Toxicity to birds *[If "Test type" =*

"reproduction toxicity" / <> "reproduction toxicity", respectively.]

Proposed test guideline: <Guideline>

Species: <Test organisms (species)>

Test type: <Test type> (<Dose method>)

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.3.5 Toxicity to birds.]*

<Discussion>

The following information is taken into account for effects on birds for the derivation of PNEC:

<Short description of key information>

Value used for CSA:

Short-term EC50 or LC50 for birds: <Short-term EC50 or LC50 for birds> <Unit>

Long-term EC10/LC10 or NOEC for birds: <Long-term EC10/LC10 or NOEC for birds> <Unit>

7.5.2. Toxicity to mammals

[IUCLID source: section 6.3.6 Toxicity to other above-ground organisms.
Sort rule in table: Field "Purpose flag" = (1) "key study"; (2) "supporting study" (3) "weight of evidence"; (4) "disregarded study".]

No relevant information available *[Rule: Print if applicable.]*

The results are summarised in the following table:

Table 103. Effects on mammals

Method	Results	Remarks	Reference
<Test organisms (species)> <Study type> <Guideline> <Principles of method if other than guideline>	<Endpoint> (<Duration>): <Effect conc.> <Conc. based on> (<Nominal/Measured>) based on: <Basis for effect> (<Remarks>)	<Reliability> <Purpose flag> <Study result type> **Test material identity [***See description of rules in introductory part.]* Form: <Test material form> [*If field is populated]*	<Author> <Year>

Data waiving

Information requirement: Effects on other above-ground organisms / mammals

Reason: <Data waiving>

Justification: <Justification for data waiving>

Testing proposal

Information requirement: Effects on other above-ground organisms / mammals

Proposed test guideline: <Guideline>

Species: <Test organisms (species)>

Study type: <Study type>

Principles of method if other than guideline:

<Principles of method if other than guideline>

Planned study period: <Study period>

Discussion *[IUCLID source: Endpoint summary 6.3.6 Toxicity to other above-ground organisms.]*

<Discussion>

The following information is taken into account for effects on mammals for the derivation of PNEC:

<Short description of key information>

Value used for CSA: Short-term EC50 or LC50 for mammals: <Short-term EC50 or LC50 for mammals> <Unit>

Value used for CSA: Long-term EC10/LC10 or NOEC for mammals: <Long-term EC10/LC10 or NOEC for mammals> <Unit>

7.6. PNEC derivation and other hazard conclusions

[IUCLID source: Endpoint summary 6. Ecotoxicological information.

Table 104. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	<Hazard assessment conclusion (freshwater)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC freshwater derivation>
Marine water	<Hazard assessment conclusion (marine waters)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC marine water derivation>
Intermittent releases to water	<Hazard assessment conclusion (intermittent releases)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC intermittent releases derivation>
Sediments (freshwater)	<Hazard assessment conclusion (sediment freshwater)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC sediment derivation>
Sediments (marine water)	<Hazard assessment conclusion (sediment marine water)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC sediment derivation>
Sewage treatment plant	<Hazard assessment conclusion (STP)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC STP derivation>
Soil	<Hazard assessment conclusion (soil)>: <PNEC value> <Unit>	Assessment factor: <assessment factor> Extrapolation method: <Extrapolation method> <Justification for (no) PNEC soil derivation>
Air	<Hazard assessment conclusion (air)>: <PNEC value> <Unit>	<Justification for (no) PNEC air derivation>
Secondary poisoning	<Hazard assessment conclusion (secondary poisoning)>: <PNEC	Assessment factor: <assessment factor> <Justification for (n) PNEC oral derivation>

	value> <Unit>	

Environmental classification justification

<Environmental classification justification> *[IUCLID source: Endpoint summary 6. Ecotoxicological information.]*

General discussion

<Discussion>

8. PBT AND vPvB ASSESSMENT

8.1 Assessment of PBT/vPvB Properties

8.1.1 PBT/vPvB criteria and justification

[IUCLID source: endpoint study record(s) of 2.3 PBT assessment]

8.1.1.n Assessed substance: <Assessed substance>
[Rule: If field "Assessed substance" is populated]

8.1.1.n Assessed substance: not specified
[Rule: If field "Assessed substance" is blank]

[Rule: A subheading with a consecutive section number is created for each substance assessed in the following order: 1. Substance itself; 2. Constituent; 3. Transformation product; 4. not specified.]

Reference substance: <Reference substance>

>>>CAUTION: Please specify the Reference Substance in the corresponding field of IUCLID section 2.3<<<
[Rule: Print default statement if field "Assessed substance" is populated with "Constituent" or "Transformation product" and field "Reference Substance" is empty.

Remark on assessed substance: <Remark>

8.1.1.n.1 Persistence assessment

*[Rule: Print the default statement(s) specified below if the corresponding checkbox(es) is/are ticked, i.e.
Checkbox 1 (Not P and not vP based on: readily biodegradable),
Checkbox 2 (Not P and not vP based on: other screening test(s) (e.g. enhanced ready biodegradability, inherent biodegradability test) under valid conditions),
Checkbox 3 ("Not P and not vP based on T1/2 ..."),
Checkbox 4 ("P but not vP based on T1/2 ...")]*

Evidence of non-P / non-vP properties *[Rule: Print subheading if checkbox 1, 2, 3 and/or 4 are ticked and/or any "Remark" field is populated in the block "Screening criteria" and/or in the block "Criteria based on Annex XIII of REACH".]*

Screening criteria *[Rule: Print subheading if checkbox 1 and/or 2 are ticked and/or any "Remark" field is populated in the block "Screening criteria".]*

- *Not P / vP based on ready biodegradability [Rule: If checkbox 1 is ticked and the related "Remark" field is empty.]*

- *Not P / vP based on ready biodegradability*: <Remark>
[Rule: If checkbox 1 is ticked and the related "Remark" field is populated.]

- Remarks on ready biodegradability: <Remark>
[Rule: If checkbox 1 is not ticked and the related "Remark" field is populated]

- Not P / vP based on other screening test(s) (e.g. enhanced ready biodegradability, inherent biodegradability) under valid conditions [Rule: If checkbox 2 is ticked and the related "Remark" field is empty.]

- Not P / vP based on other screening test(s) (e.g. enhanced ready biodegradability, inherent biodegradability) under valid conditions: <Remark>
[Rule: If checkbox 2 is ticked and the related "Remark" field is populated.]

- Remarks on other screening test(s) (e.g. enhanced ready biodegradability, inherent biodegradability) under valid conditions: <Remark>
[Rule: If checkbox 2 is not ticked and the related "Remark" field is populated.]

Criteria based on Annex XIII of REACH *[Rule: Print subheading if checkbox 3 is ticked and any or all related "Remark" field(s) are populated in the block "Criteria based on Annex XIII of REACH".]*

- Not P / vP based on criteria laid down in Annex XIII of REACH:
[Rule: If checkbox 3 is ticked.]

- *T1/2 <= 60 days in marine water*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion:]* >>>**CAUTION:** Please complete the corresponding "Remark" field in IUCLID for this T1/2 criterion. Please note: If the substance is not P and not vP based on criteria laid down in Annex XIII of REACH, then it has to be confirmed that all T1/2 criteria are fulfilled. In case no appropriate half-life data are available, justify that the half-life is expected to comply with the given criteria.<<<

- *T1/2 <= 40 days in fresh- or estuarine water*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion]* >>>**CAUTION:** "Remark" field ...<<<

- *T1/2 <= 180 days in marine sediment*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion:] >>>CAUTION: "Remark" field ...<<<*

- *T1/2 <= 120 days in fresh- or estuarine sediment*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion:] >>>CAUTION: "Remark" field ...<<<*

- *T1/2 <= 120 days in soil*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion:] >>>CAUTION: "Remark" field ...<<<*

- Remarks on Annex XIII criteria (P/vP): *[Rule: If checkbox 3 is not ticked and at least one of the related "Remark" fields is populated.]*
[Rule for items listed: Each bulleted item is printed if the corresponding "Remark" field is populated.]

- *T1/2 <= 60 days in marine water*: <Remark>
- *T1/2 <= 40 days in fresh- or estuarine water*: <Remark>
- *T1/2 <= 180 days in marine sediment*: <Remark>
- *T1/2 <= 120 days in fresh- or estuarine sediment*: <Remark>
- *T1/2 <= 120 days in soil*: <Remark>

- P but not vP based on criteria laid down in Annex XIII of REACH: *[Rule: If checkbox 4 is ticked.]*

- *T1/2 <= 60 days in marine, fresh- or estuarine water*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion]* **>>>CAUTION:** Please complete the corresponding "Remark" field in IUCLID for this T1/2 criterion. Please note: If the substance is P but not vP based on criteria laid down in Annex XIII of REACH, then it has to be confirmed that all T1/2 criteria are fulfilled. In case no appropriate half-life data are available, justify that the half-life is expected to comply with the given criteria.<<<

- *T1/2 <= 180 days in marine, fresh- or estuarine sediment*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion]* >>>**CAUTION:** "Remark" field ...<<<

- *T1/2 <= 180 days in soil*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the T1/2 criterion]* >>>**CAUTION:** "Remark" field ...<<<

- Remarks on Annex XIII criteria (P/vP): *[Rule: If checkbox 4 is not ticked and at least one of the related "Remark" fields is populated.]*
[Rule for items listed: Each bulleted item is printed if the corresponding "Remark" field is populated.]

- *T1/2 <= 60 days in marine, fresh- or estuarine water*: <Remark>
- *T1/2 <= 180 days in marine, fresh- or estuarine sediment*: <Remark>
- *T1/2 <= 180 days in soil*: <Remark>

Other evidence of non-P / non-vP properties *[Rule: Print if the corresponding "Remark" field is populated.]*

<Remark>

Further information is necessary to conclude on the P or vP properties in the context of the PBT assessment *[Rule: Print if the corresponding "Remark" field is populated.]*

<Remark>

Evidence of P or vP properties *[Rule: Print if the corresponding "Remark" field is populated.]*

<Remark>

Conclusion on P / vP properties: <Conclusion on P / vP properties>
[Rule: Print content of this IUCLID field. If not populated, print the following warning statement after the prompt:]
>>>CAUTION: Please complete the corresponding IUCLID field by selecting the appropriate conclusion for the P assessment.<<<

<Remark>

8.1.1.n.2 Bioaccumulation assessment

*[Rule: Print the following default statement(s) below if the corresponding checkbox(es) is/are ticked, i.e.
Checkbox 1 (Not B and not vB based on: Log Kow <= 4.5"),
Checkbox 2 (Not B and not vB based on: BCF <= 2000 L/kg"),
Checkbox 3 ("B but not vB based on: 2000 < BCF <= 5000 L/kg")]*

Evidence of non-B / non-vB properties *[Rule: Print subheading if checkbox 1, 2 and/or 3 are ticked and/or any "Remark" field is populated in the block "Screening criteria" and/or in the block "Criteria based on Annex XIII of REACH".]*

Screening criteria *[Rule: Print subheading if checkbox 1 is ticked and/or "Remark" is populated.]*

- Not B / vB based on Log Kow <= 4.5 [Rule: If checkbox 1 is ticked and the related "Remark" field is empty.]

- Not B / vB based on Log Kow <= 4.5: <Remark> *[Rule: If checkbox 1 is ticked and the related "Remark" field is populated.]*

- Remarks on criterion "Log Kow <= 4.5": <Remark> *[Rule: If checkbox 1 is not ticked and the related "Remark" field is populated.]*

Criteria based on Annex XIII of REACH *[Rule: If checkbox 2 and/or 3 is ticked and/or any of the related "Remark" fields is populated.]*

- Not B / vB based on BCF <= 2000 L/kg [Rule: If checkbox 2 is ticked and the related "Remark" field is empty.]

- Not B / vB based on BCF <= 2000 L/kg: <Remark> *[Rule: If checkbox 2 is ticked and the related "Remark" field is populated.]*

- Remarks on criterion "BCF <= 2000 L/kg": <Remark> *[Rule: If checkbox 2 is not ticked and the related "Remark" field is populated.]*

- B but not vB based on 2000 < BCF <= 5000 L/kg [Rule: If checkbox 3 is ticked and the related "Remark" field is empty.]

- B but not vB based on 2000 < BCF <= 5000 L/kg: <Remark> *[Rule: If checkbox 3 is ticked and the related "Remark" field is populated.]*

- Remarks on criterion "2000 < BCF <= 5000 L/kg": <Remark> *[Rule: If checkbox 3 is not ticked and the related "Remark" field is populated.]*

Other evidence of non-B / non-vB properties *[Rule: If the corresponding "Remark" field is populated.]*

<Remark>

Further information is necessary to conclude on the B or vB properties in the context of the PBT assessment *[Rule: If the corresponding "Remark" field is populated.]*

<Remark>

Evidence of B or vB properties *[Rule: Print if the corresponding "Remark" field is populated.]*

<Remark>

Conclusion on B / vB properties: <Conclusion of B / vB properties>
[Rule: Print content of this IUCLID field. If not populated, print the following warning statement after the prompt:]
>>>CAUTION: Please complete the corresponding IUCLID field by selecting the appropriate conclusion for the B assessment.<<<

<Remark>

8.1.1.n.3 Toxicity assessment

[Rule: Print the following default statements depending on the checkboxes ticked, i.e.
Checkbox 1 (Not T based on…),
Checkbox 2 "Evidence of T properties: Screening criteria (L(E)C50 <0.01 mg/L)"
Checkbox 3 "Evidence of T properties: other evidence"]

Evidence of non-T properties *[Rule: Print subheading if checkbox 1 is ticked and/or any related text fields are populated.]*

Criteria based on Annex XIII of REACH *[Rule: If checkbox 1 is ticked and/or any related text fields are populated.]*

- Not T based on criteria laid down in Annex XIII of REACH: *[Rule: If checkbox 1 is ticked.]*

- *EC10 / NOEC >= 0.01 mg/L for marine / freshwater organisms (long-term toxicity)*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the prompt:]* >>>**CAUTION:** Please complete the corresponding "Remark" field in IUCLID for this criterion. Please note: If the substance is not T based on criteria laid down in Annex XIII of REACH, then it has to be confirmed that all criteria are fulfilled. If data are lacking, justify that long-term toxicity to marine and freshwater organisms is expected to be >= 0.01 mg/L.<<<

- *Substance is not classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3) according to Directive 67/548/EEC (or the DSD) or carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to Regulation EC No 1272/2008 (or CLP Regulation) (see also section "3. Classification and labelling")*: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the prompt:]* >>>**CAUTION:** Please complete the corresponding "Remark" field in IUCLID for this criterion. Please note: If the substance is not T based on criteria laid down in Annex XIII of REACH, then it has to be confirmed that all criteria are fulfilled. If data are lacking, justify that long-term toxicity to marine and freshwater organisms is expected to be >= 0.01 mg/L.<<<

- *No other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC or specific target organ toxicity after repeated exposure (STOT RE*

category 1 or 2) according to Regulation EC No 1272/2008: <Remark> *[Rule: If the "Remark" field is populated. Otherwise print the following warning statement after the prompt:]* >>>**CAUTION:** Please complete the corresponding "Remark" field in IUCLID for this criterion. Please note: If the substance is not T based on criteria laid down in Annex XIII of REACH, then it has to be confirmed that all criteria are fulfilled. If data are lacking, justify that long-term toxicity to marine and freshwater organisms is expected to be >= 0.01 mg/L.<<<

- Remarks on Annex XIII criteria (T): *[Rule: If checkbox 1 is not ticked and at least one of the related "Remark" fields is populated.]*

- *EC10 / NOEC >= 0.01 mg/L for marine / freshwater organisms (long-term toxicity)*: <Remark> *[Rule: If the "Remark" field is populated.]*

- *Substance is not classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3) according to Directive 67/548/EEC (or the DSD) or carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to Regulation EC No 1272/2008 (or CLP Regulation) (see also section "3. Classification and labelling")*: <Remark> *[Rule: If the "Remark" field is populated.]*

- *No other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008*: <Remark> *[Rule: If the "Remark" field is populated.]*

Other evidence of non-T properties *[Rule: If the corresponding "Remark" field is populated.]*

<Remark>

Further information is necessary to conclude on the T properties in the context of the PBT assessment *[Rule: If the corresponding "Remark" field is populated.]*

<Remark>

Evidence of T properties *[Rule: Print if checkbox 2 and/or 3 are ticked and/or the corresponding "Remark" field is populated.]*

Screening criteria (L(E)C50 <0.01 mg/L) fulfilled *[Rule: Print if checkbox 2 is ticked.]*

Other evidence *[Rule: Print if checkbox 3 is ticked.]*

Remark: <Remark> *[Rule: Print if "Remark" field is populated.]*

Conclusion on T properties: <Conclusion on T properties>
[Rule: Print content of this IUCLID field. If not populated, print the following warning statement after the prompt:]
>>>CAUTION: Please select from the pick-list the appropriate conclusion for the T assessment.<<<
<Remark>

8.1.2 Summary and overall conclusions on PBT or vPvB properties

[IUCLID source: endpoint summary 2.3 PBT assessment, unless otherwise stated]

Overall conclusion:

Based on the assessment described in the subsections above the submission substance is not a PBT / vPvB substance. *[Rule: If "The substance is not PBT / vPvB" is selected in source field "PBT assessment: overall result".]*

Based on the assessment described in the subsections above the submission substance is a PBT / vPvB substance. *[Rule: If "The substance is PBT / vPvB" is selected in source field "PBT assessment: overall result".]*

The submission substance is handled as if it were a PBT / vPvB substance. *[Rule: If "The substance is handled as if it were a PBT/vPvB" is selected in source field "PBT assessment: overall result".]*

PBT assessment does not apply. *[Rule: If "PBT assessment does not apply" is selected in source field "PBT assessment: overall result".]*

Further information relevant for the PBT assessment is necessary. *[Rule: If "Further information relevant for the PBT assessment is necessary" is selected in source field "PBT assessment: overall result".]*

>>>**CAUTION**: Please complete the field "PBT assessment: overall result" in the endpoint summary for IUCLID section 2.3 by selecting the appropriate conclusion from the picklist.<<< *[Rule: If source field "PBT assessment: overall result" is empty.]*

>>>CAUTION: Check if the overall conclusion "non-PBT/non-vPvB" is consistent with the PBT criteria given in IUCLID section 2.3. Not all fields "Conclusion on P/vP (or B/vB or T) properties" indicate "not P/vP", "not B/vB" and "not T", respectively.<<< *[Rule: Print if "The substance is not PBT / vPvB" is selected in source field "PBT assessment: overall result" AND neither field "Conclusion on P / vP properties" = "not P/vP" nor "Conclusion on B / vB properties" = "not B/vB" nor "Conclusion on T properties" = "not T" in the endpoint study records of section 2.3. This pertains to all assessed substances, i.e. substance itself, constituent and/or transformation product.]*

Justification: <Justification>
[Rule: Print paragraph only if the corresponding source field is populated]

Justification: >>>CAUTION: Please complete the field "Justification" in the endpoint summary for IUCLID section 2.3<<< *[Rule: Print if the corresponding source field is empty and either the conclusion "The substance is not PBT/vPvB", "Further information relevant for the PBT assessment is necessary" or "PBT assessment does not apply" in field "PBT assessment: overall result".]*

8.2 Emission characterisation

[Rule: Print subsection only if "The substance is PBT / vPvB"or "The substance is handled as if it were a PBT/vPvB" is selected in source field "PBT assessment: overall result".]

Operational conditions and risk management measures:

The operational conditions and risk management measures put in place are reported in the exposure scenarios in section 9.

Residual releases

The total release and emissions values are reported in section 9.

Likely routes by which humans and the environment are exposed:

<Likely routes of exposure>

>>>CAUTION: Complete the corresponding field in the endpoint summary of IUCLID section 2.3<<< *[Rule: Print this default statement if this field is empty.]*

Justification of minimisation of emission/exposure:

The justification of the minimisation of emissions and (subsequent) exposures of humans and the environment is reported in sections 9 and 10.

9. EXPOSURE ASSESSMENT

[Rule: This heading is printed if the option "Select a Chesar file" is skipped in step 2 of the CSR generation process, that is, only IUCLID data are captured. In this case only subheadings are printed with no information except for the following note and table, which occurs under the subheading 9.0. Introduction - 9.0.1. Overview of uses and Exposure Scenarios.]

>>>NOTE: As the Chesar tool has not been used for generating this CSR, the "Brief description of use process" is reported below as provided in IUCLID section 3.5 for each use identified in CSR section 2.2. Such information may be reported within each exposure scenario.<<< *[Rule: Print if if any field specified in the table is populated.]*

Table 105. Brief description of the use process for all identified uses
[Rule: A separate row is generated for each use with the following order: first Formulation, second Uses at industrial sites, third Uses by professional workers.]

Identified use	Brief description of use process
Confidential:*[Rule: Print if Confidentiality flag = CBI]* #-<Identified use number>: <Identified use name> *[Rule: Instead of # the relevant acronym is printed, i.e. F-, IW-, PW-]* *[e.g. F-2: Formulation of liquid mixtures]*	<Brief description of use process>

9. EXPOSURE ASSESSMENT (AND RELATED RISK CHARACTERISATION)

[Rule: This heading is printed if the option "Select a Chesar file" is choosen in step 2 of the CSR generation process, that is, both IUCLID and Chesar data are captured. In this case the CSR section 9 is generated and filled with Chesar information as described in the Chesar user manual part 4.]

10. RISK CHARACTERISATION

[Rule: This heading is printed if the option "Select a Chesar file" is choosen in step 2 of the CSR generation process, that is, both IUCLID and Chesar data are captured. In this case the CSR section 10 is generated and filled with Chesar information as described in the Chesar user manual part 4.]

REFERENCES

[At the end of the CSR a list of all references cited is printed.]

European Chemicals Agency

IUCLID 5 Guidance and Support

CSR plug-in for IUCLID 5.4
User Manual
February 2013 version 4.1

http://iuclid.eu